

June 23, 2006

CMS – 1270 – P Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS – 1270 – P Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

Gentlemen:

I am writing in reference to the Competitive Bidding Proposal that will be voted on this year. There are several points that I feel very strongly about and I firmly believe that you are venturing into very dangerous territory. You will be limiting the quality of equipment that is available. Additionally, you will cause the "most needy" portion of the population to be at the mercy of suppliers who you have been chosen based on price. This is not the way I wish to end my years. I do not wish to have to settle because the government is trying to save money. This means, as always, those with expendable income will be able to purchase a better grade of equipment. Anyone who has to depend on Medicare will have to make do. This is patently unfair and you, as a governing body are about to foist this upon an unsuspecting public.

Please take a few minutes to consider what I propose.

- 1. Allow time for all bidders to be considered and the price(s) they quote, along with their explanation for same. (By this I mean that they need to be able to factor in the time to assemble and explain the use of the item/equipment they are delivering). Please be very aware that DME Providers spend a great deal of time "holding the hands" of clients in terms of reassuring them that a piece of equipment is functioning correctly. In addition, it is sometimes necessary to go their home and reassure them that there is not a problem, or if there is, make the necessary repairs. Please be aware that some of these clients are in such condition that they cannot leave their home readily and one of our representatives is like having "company" and they will talk and talk (on the phone or in person). This is a service that does not come with a price tag, and we do it willingly.
- 2. Do not cater to the large DME providers to the exclusion of the small dealers (who are to be found in small, sometimes out-of-the-way locations). If you only rely on the larger providers, the clients who live in the fringe communities or in out-of-the-way locations will not be served because they require a great deal of time to get to and return. Of course they could become like the "Scooter Store" and drop ship the needed items. However, if it is incorrect or does not work, then what does a client do, especially if they are in real need? Most suppliers have provisions in place to handle emergencies, 24/7. We have had personnel that went out of the way on their drive home to drop off, pick up or swap out a piece of equipment. Again, this is not a service that has a price tag attached. We "know and value" our clients. Some have been with us for a long period of time and we, in effect, become like family.

Someone who is in this business strictly for the money, or who is trying to conserve "every penny" because he won the **low bid** for an item, is not going to go out of his way. Every trip out and back will cost extra money, money he will not be reimbursed for. There is no incentive to do anything extra, in fact there is more incentive to "cut corners". Then the consumer is the loser, as I suggested earlier.

3. Do not split categories. What I mean is if a provider "wins" the bid for hospital beds, then they should also be allowed to carry the related items. This holds true for wheelchairs and other such equipment that has necessary and related accessories.

These are just a few of my thought. I definitely do not like the idea of competitive bidding, as you can tell. I sincerely believe that it will become rife with problems and abuses. Then we will have to come up with more costly methods to repair it. My feeling is, it really is not broken, why do you feel the need to fix it? Most certainly, the current system can be improved upon, but not to such an extent that it will be so totally changed.

Thank you for taking the time to read and consider my suggestions. I look forward to your response.

Respectfully, Joan B. Levrees

Joan B Curcio 19 Barn Owl Drive

Hackettstown, N J 07840

Cc: Congressmen

June 28, 2006





Hon. Mark B. McClellan, M.D., PhD. Administrator Centers for Medicare and Medicaid Services, Department of Health and Human Services 7500 Security Boulevard Attention: CMS – 1270-P Mail Stop C4-26-05 Baltimore, MD 21244-1850

Re: Comments on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule (Docket Number CMS-1270-P)

Dear Dr. McClellan:

Roche Diagnostics is pleased to submit comments on the Proposed Rule on the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. We have manufactured diabetes care test systems for almost 30 years and have an insulin pump business.

Roche Diagnostics believes that CMS should either delay competitive bidding for diabetes care self-test systems or at minimum, severely limit the size of the competitive bidding area for these products. We do not make this recommendation lightly and are well aware of the need for CMS to demonstrate cost savings. To support our position, Roche Diagnostics makes the following observations:

Diabetes Self-Test Care Systems are Different from Other Types of DME

- They are interactive not passive devices.
- Diabetes care systems are a cornerstone of primary care in the management of diabetes and are used by beneficiaries to run tests – sometimes many times daily – on which treatment regimens are based and continually adjusted. The Agency for Healthcare Research and Quality reported that Medicare could save \$1.3B annually if beneficiaries with diabetes received appropriate primary care.

- Compliance with diabetes care testing is difficult to achieve for many reasons it may be painful, embarrassing, inconvenient, hard to perform, or not recognized as a priority because like high blood pressure, diabetes is often a silent disease.
- Ultimately, failure to test results in devastating complications. It is these complications, not testing, that account for the burden of costs in diabetes care.
- Health care providers physicians, diabetes educators and pharmacists work with the beneficiary in selecting the best test system that will meet his or her needs, thereby increasing testing compliance.
- Most first time users of diabetes care systems must be trained to operate the new system and manage their care based on the results.
- Health care providers educate and train the patient in the use of blood glucose test systems.
- Many beneficiaries need continuing assistance with blood glucose monitoring.

Diabetes Affects America's Sickest and Most Vulnerable Seniors

- Nearly 1/3 of Medicare costs support beneficiaries with diabetes. A significant number of these individuals have other comorbidities, reduced cognition, poor literacy, or are low income dual eligibles.
- Diabetes affects a disproportionate share of minority beneficiaries. Behaviors and communications toward managing the disease can differ significantly among these populations.

Changes in Distribution and Products Could Adversely Impact Thousands of Beneficiaries

 Distribution systems for diabetes care products are significantly different than other types of DME. Sixty percent of beneficiaries acquire supplies Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 3 of 24

at their local pharmacy often at the same time their prescriptions are being filled. The remaining obtain their supplies via mail order.

- The number of beneficiaries in a large MSA who would require any singular item of DME will pale in comparison to the number of beneficiaries with diabetes who will need to switch out their blood glucose test systems.
- Health care providers will be responsible for carrying the burden of educating and retraining beneficiaries who must switch systems in competitive bidding areas.

Neither of the two competitive bidding demonstration projects tested diabetes care self test systems or similar kinds of devices. It is unknown, therefore, the impact that competitive bidding will have on the parameters listed above or how the resultant changes to some of these parameters will be accommodated. Due to the thousands of beneficiaries and health care providers who will be significantly impacted by a large competitive bidding program, we urge CMS to give serious consideration to our request to delay or to restrict a competitive bidding program for diabetes test systems. This will allow the Agency time to gain experience.

Roche Diagnostics believes that CMS should consider exempting insulin pump systems from the competitive bidding program. If the Agency decides not to exempt these products, we recommend that a competitive bidding program for insulin pump systems be delayed or limited to a small area in order for CMS to gain experience with these items. To support these recommendations, we would like CMS to consider the following:

Insulin Pump Systems are Low Volume Complex Devices

- Like diabetes care self test systems, insulin pump systems are interactive not passive devices.
- Many beneficiaries need continuing assistance with insulin pump maintenance and operation and must play a direct role by calibrating insulin administration to blood glucose levels.

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 4 of 24

- Insulin pump systems are a low volume product in the Medicare system only 10% of beneficiaries with Type I diabetes use these products. As CMS is aware, Type I diabetes represents only 5-10 percent of the cases overall and the number of Type I cases is growing much more slowly than Type II cases.
- We do not expect that Medicare costs for insulin pump systems will grow significantly any time soon due to CMS' recent national coverage decision which would preclude the use of these products for beneficiaries with Type II diabetes. In addition, these are relatively complex products and cannot be used by all beneficiaries with diabetes. As CMS has noted in its national coverage decision, insulin pumps —

"do not measure blood glucose levels or automatically adjust insulin delivery rates. For proper effect, the...user must measure blood glucose several times per day and program the pump to deliver an appropriate basal rate and pre-meal boluses of insulin. Because of this, not all patients are candidates for [pump-based therapy].

Compared to Typical DME Products, the Supplier Market is Different and Significantly Limited

- In its Proposed Rule, CMS has proposed as a criterion a high ratio of suppliers to beneficiaries. The insulin pump market is supplied primarily by four manufacturers. For the most part, the manufacturers distribute these products directly to the beneficiaries; thus, the ratio of suppliers to beneficiaries is low.
- Excluding any of the four suppliers from the market through competitive bidding could reduce competition.

Neither of the two competitive bidding demonstration projects included insulin pump systems or similar kinds of devices. It is unknown, therefore, the impact that competitive bidding will have on the parameters listed above or how the resultant changes to some of these parameters will be accommodated. In addition, these are low volume complex devices obtained from a very limited number of suppliers. Because of this, Roche Diagnostics recommends that insulin pump systems be excluded from the competitive

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 5 of 24

bidding program. If CMS does decide to seek competitive bids for these products, we recommend that the competitive bid area be limited in order to give the Agency experience in this area.

Below are Roche Diagnostics' comments on specific provisions of the Proposed Rule.

I. Background

D. Medicare Competitive Bidding Demonstrations

Competitive Bidding of Blood Glucose Systems Should Be Delayed or Limited Until CMS Gains Further Knowledge of the Impact of the Program

CMS states that the competitive bidding demonstration programs in Polk County, Florida and San Antonio, Texas achieved "mostly successful results" and that "statistical and qualitative data" indicate that beneficiary access and quality of services were essentially unchanged." We are aware however, of the many problems that CMS encountered, particularly with urological supplies. We are also not aware of any CMS issuances to the public on the detailed statistical, quantitative and qualitative methodologies that were used by the Agency in analyzing the degree to which beneficiary access and quality of products and services was determined. We acknowledge that the purpose of a demonstration project is to ferret out problematic areas such as those identified with urological supplies, but are very concerned that the Agency did not grasp the nature of these items at a very fundamental level prior to incorporating them into the program. We make these observations in light of the unique issues that are presented by blood glucose systems. We believe that the Agency must be able to accurately measure not only the savings achieved by the competitive program but also overall affect on beneficiaries in terms of the quality of care and reduction of clinical costs.

As CMS is aware from our November 23, 2005 comments to the Agency on the Quality Standards (included with these comments), diabetes test systems are entirely different from other types of DME. They are mostly acquired at retail outlets when other prescriptions are being filled, can require significant support in terms of education and compliance, and are a diagnostic tool that must be used on a daily basis to prevent extremely devastating and costly clinical complications. We firmly believe that changing these systems on a mass scale

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 6 of 24

will be an extremely unsettling process for the tens of thousands of beneficiaries affected and could result in unintended and costly consequences – most notably an increase in physician office and emergency room visits, inpatient admissions and an increase in complications such as retinopathy, blindness, kidney disease and failure, cardiovascular disease and amputations.

We strongly recommend that CMS give serious consideration to delaying competitive bidding for diabetes care products or to limiting competitive bidding to a very small area until the Agency gains sufficient experience with products that are less complex. In addition, we believe that CMS should be able to detect and measure untoward clinical events in a statistically valid manner. The Agency should state the methodologies that will be used to accomplish this in its next issuance of the competitive bidding rule.

F. Deficit Reduction Act of 2005

As CMS acknowledges in its Proposed Rule, section 5101(a) of the Deficit Reduction Act of 2005 (DRA) amends the Social Security Act to effect changes in the way Medicare pays for certain capped rental items. What CMS does not acknowledge is the greater level of complexity that beneficiaries will face as they attempt to manage their diabetes amid the combined effects of the new competitive bidding and DRA changes.

DRA provides for transfer of title of capped rental items from suppliers to beneficiaries for those items for which the first month of rental occurs on or after January 1, 2006. Such transfer is required to occur after 13 continuous months of rental. These DRA-required changes, even standing alone, raise serious questions about how beneficiaries will ensure adequate maintenance and service for their pumps. If combined with the new competitive bidding program, beneficiaries will encounter even greater uncertainty about maintenance and service.

As CMS notes in the Proposed Rule, the implementation of the DRA's cappedrental changes will be the subject of a future rulemaking. We therefore suggest, at a minimum, that CMS defer considering application of competitive bidding to insulin pump systems until these DRA changes are implemented in final regulations.

To illustrate the importance of such a deferral, consider the fact that one issue the DRA regulations will address is the basis upon which Medicare will make Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 7 of 24

statutorily mandated payments for the maintenance and servicing of capped rental equipment after title to that equipment has passed to a beneficiary. Until CMS has deliberated on stakeholder comments and finalized its approach to these payments, the Agency's competitive bidding structure for insulin pump systems is necessarily clouded and ambiguous, adding another layer of uncertainty for beneficiaries.

In all, CMS should at a minimum defer competitive bidding of insulin pumps systems at least until the DRA changes are finalized. Such a deferral would allow CMS to structure payments for insulin pump systems coherently and holistically, thereby allowing suppliers and beneficiaries to understand the full reimbursement parameters before bidding begins.

G. Program Oversight and Advisory Committee

CMS Should Fulfill the MMA Mandate to Develop Proposals on the Efficient Interaction among Manufacturers, Providers, Suppliers and Individuals

Due to the unique circumstances surrounding diabetes care and access to supplies, Roche Diagnostics believes that the PAOC meetings did not adequately address the "efficient interactions among manufacturers, providers of services, suppliers and individuals." In the diabetes disease management continuum, all of these entities work closely with each other and the beneficiary to train, provide support services and monitor the patient with the objective of maintaining an optimal clinical status. We are aware of only one PAOC panel that was devoted to diabetes. This panel primarily focused on supplier issues and not the relationship between the key entities in the diabetes care continuum. We are also not aware of any meetings between CMS or RTI with national supplier, provider and manufacturer organizations to discuss the impact that competitive bidding will have on the interaction of these groups and the effect on the day to day management of beneficiaries with diabetes. Roche Diagnostics notes that failure to meet with these stakeholders to specifically discuss what we consider to be a fairly complex chain of interactions has resulted in Quality Standards that do not reflect the current standards of care for diabetes. The Proposed Rule raises these same issues and concerns. We recommend that these interactions be addressed prior to the second issuance of the Quality Standards and the competitive bidding rule.

H. Quality Standards for Suppliers

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 8 of 24

CMS Should Work with National Supplier and Provider Organizations and Beneficiaries with Diabetes to Develop Standards that will Result in Quality Products and Care

Roche Diagnostics agrees that CMS should only award competitive bidding contracts to those suppliers who are in compliance with the Quality Standards. Due to the significant shortcomings in the first draft of the standards with regard to diabetes care systems, however, we question whether CMS can realistically issue a final version that will meet its stated competitive bidding implementation timeline. As noted earlier in these comments, we submitted extensive comments to the Agency on the Quality Standards. In general, we believe that the standards need to be modified significantly in order to ensure that minimal disruptions occur in care. Beneficiary access to quality diabetes products should be guaranteed and adequate safeguards should be in place to prevent the use of counterfeit or substitute products. There should not be undue encouragement or pressure on beneficiaries to obtain additional products if they are not needed. In developing the Quality Standards - and as recommended to the Agency in our comments on the Quality Standards - we strongly recommend that CMS adhere to its statement in the Proposed Rule that says "We are using contractor support and input from industry suppliers and national organizations to develop the quality standards. Additionally, the contractors will meet with beneficiaries who use the specific products to solicit their input..."

The Quality Standards Should be Treated as a Rule

Roche Diagnostics believes that due to the impact the Quality Standards will have on tens of thousands of suppliers (many of whom are small), CMS should perform an economic impact analysis and comply with the Regulatory Flexibility Act. Because CMS did not apply formal notice and comment to the Quality Standards, we also believe that CMS should comply with the Congressional Review Act. Additionally, because compliance with the Quality Standards will result in the generation of new forms, the burden and necessity of these should be analyzed by CMS and submitted to the OMB Office of Information and Regulatory Affairs as per the requirements of the Paperwork Reduction Act.

I. Accreditation for Suppliers of DMEPOS and Other Items

Roche Diagnostics agrees that CMS should follow the Administrative Procedure Act with an opportunity for comment when issuing the procedure for designating and supervising accreditation agencies. We also support CMS' proposal that those suppliers who are currently accredited be grandfathered in.

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 9 of 24

K. Establishing Fee Schedule Amounts for New DMEPOS Items

This is an extremely important proposal that is not related to competitive bidding. Roche Diagnostics does not believe that this should be included in the Proposed Rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

M. Covered Item Updates for Class III DME for Class III DME for CYs 2007 and 2008

This is an extremely important proposal that is not related to competitive bidding. Roche Diagnostics does not believe that this should be included in the proposed rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

II. Provisions of the Proposed Regulation

B. Implementation Contractor

Roche Diagnostics supports the CMS decision to use Competitive Bidding Contractors to implement the competitive bidding program.

C. Payment Basis

3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers)

a. Process for Grandfathering Suppliers

Roche Diagnostics supports the CMS proposal to allow continuation of rental agreements by suppliers who have furnished supplies prior to the start of the competitive bidding program in an area (or prior to the start of a subsequent round of a competitive bidding program in an area), but disagrees with making completion of the rental agreement for grandfathered items optional. Making completion of an established rental agreement optional has no benefit to the beneficiary. This would result in abrupt transitions from grandfathered suppliers to other suppliers, causing increased short-term costs to the Medicare program that would be incurred through the clinical disruption to diabetes care.

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 10 of 24

These disruptions can be substantial. Roche Diagnostics, for example, provides 70 percent of its pumps directly to beneficiaries and provides beneficiaries extensive training – often conducted face-to-face, complemented by 24-hour support-line assistance. Beneficiaries removed from this training and support network would therefore find it difficult to maintain quality care on a continuing and seamless basis.

Thus, transitioning to new suppliers before expiration of the rental period could lead to delayed care. It might also require retraining on new products if the new suppliers do not offer the same products on which beneficiaries had previously relied. Complicating any such transition is the fact that it is not the insulin pump alone on which a beneficiary is trained and supported, but also associated insulin cartridges (to be inserted into the pump) and infusion sets (tubes and needles to facilitate infusion of insulin into the beneficiary). Thus, an "infusion pump" is actually an interrelated system of technology and supplies. A beneficiary cannot easily transition from one system to another.

In addition to increased training costs, there could be considerable financial loss associated with the technology itself. Specifically, FDA regulations discourage the reuse of a pump removed before expiration of the rental period by another beneficiary, despite the fact that the product retains useful life. These additional accelerated costs would need to be offset against any savings competitive bidding would purportedly yield.

b. Payment Amounts to Grandfathered Suppliers

(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in an Area

Roche Diagnostics supports CMS' proposal to allow grandfathered suppliers to complete the terms of capped-rental rental agreements for DMEPOS supplied prior to implementation of the first competitive bidding program in an area at the fee schedule amount and not at the amount produced by competitive bidding. For additional comments, please refer to II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

(2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 11 of 24

Roche Diagnostics believes that suppliers that lose their contract status in a subsequent competitive bidding should be allowed to complete the terms of rental agreements at the single payment amount that was effective at the time the rental agreement began, and not be required to accept payments at the subsequent competitive bidding program single payment amount rate in order to continue to supply the capped-rental item. For additional comments, please refer to section II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

c. Payment for Accessories for Items Subject to Grandfathering

Roche Diagnostics supports the proposal to allow grandfathered suppliers to continue to supply the accessories to the grandfathered DME items at the fee schedule amount in effect prior to the start of a competitive bidding program in an area. For additional comments, please refer to II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

4. Payment Adjustment to Account for Inflation

Suppliers Should Consider Inflation When Determining Bids

Roche Diagnostics appreciates the intent behind CMS' willingness to adjust competitive bidding payment amounts for inflation. We note, however, that the Agency may not be able to control this process. We wonder, therefore, if it is wise to advise suppliers not to consider inflation when determining bids unless CMS can guarantee that it will be taken into account as part of its competitive bidding contracts.

5. Authority to Adjust Payment in Other Areas

Payment Adjustment Should Not Be Considered Until the Full Program has Been Established and Should Be Implemented Through Rulemaking Roche Diagnostics believes that there are numerous factors that must be considered before a process can be established that allows competitively bid prices to be applied to other areas. Virtually all businesses — including payers recognize the distinct differences in the cost of providing items and services in various areas of the U.S. Some of these include overhead, wage index, disproportionate share, malpractice, cost of living, service, and demographic mixes. From a diabetes care perspective, many of these elements will be

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 12 of 24

significantly different between small independent pharmacies, pharmacies that operate as part of a large retail chain and mail order. Roche Diagnostics recommends that until the competitive bidding program has been fully implemented and evaluated, this approach should not be considered. The potential for negatively impacting beneficiary access to quality products and harming thousands of suppliers is too great. If CMS does consider this approach, we believe that the process should be proposed through notice and comment rulemaking.

6. Requirement to Obtain Competitively Bid Items from a Contract Supplier

CMS Must Ensure Against Barriers to Access

The majority of Medicare beneficiaries with diabetes receive their supplies from local retail pharmacies. CMS will need to implement a very aggressive educational program that explains all of the circumstances that may limit beneficiary access to products though familiar distribution channels. Of particular importance will be an explanation as to why a beneficiary who obtains supplies from a national retail chain in their area of residence cannot receive those supplies from that same retailer when in another area - whether or not it is close to home. This may be especially difficult when the beneficiary can receive his or her prescription drugs covered under Part D Medicare (or by another payer) from that retailer - either at home or when in another location. CMS must also make available a complete listing of competitive bidding suppliers for beneficiaries who travel. To ensure that access is not compromised, Roche Diagnostics strongly recommends that CMS adopt the TriCare Pharmacy Access Standards, as was done with Medicare Part D. Last, we recommend that CMS address the situation concerning beneficiaries who have Medicare as a secondary payer and their primary payer requires them to obtain supplies from its contracted supplier. We recommend that in instances where this occurs, there should be an exclusion to competitive bidding rules since a relatively small population is affected.

D. Competitive Bidding Areas

1. Proposed Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 13 of 24

The Special Needs of Minority Populations should be considered in MSA Selection

Diabetes affects minority populations in disproportionate numbers. Theses populations are in many respects entirely different from one another, not only in their behavior toward their disease but also in the need for differentiated communications. CMS should be cognizant of these differences as it monitors and evaluates any competitive bidding areas containing minority populations.

2007 MSA Selection Criteria should be applied in 2009

The initial criteria used to select MSAs in 2007 should be applied to the 2009 selection. CMS must build in adequate time to measure and assess beneficiary access and quality of care under the 2007 program before considering any changes to MSA selection criteria. Roche Diagnostics believes that a proper analysis for diabetes – especially the effects on access and quality of care - cannot be performed prior to the 2009 MSA selection.

2. Establishing Competitive Bidding Areas

CMS Should Not Require Mail Order for Beneficiaries in Areas within Urban Areas Having Low Population Density

In applying the provision in the MMA whereby CMS can exempt from competitive bidding areas with low population density within urban areas that are not competitive unless there is a significant national market through mail order, the Agency must be cognizant of the number of minorities and low income or dually enrolled beneficiaries in that area and their unique needs. In this instance, we believe that requiring mail order as a sole source for obtaining diabetes supplies will have negative consequences.

a. Authority to Exempt Rural Areas and Areas with Low Population Density within Urban Areas

CMS Must Better Define a Noncompetitive Market

CMS needs to better define the criteria it will use in determining a noncompetitive area – low utilization, population density, and a low number of suppliers does not mean that a market is noncompetitive.

b. Establishing the Competitive Bidding Areas for 2007 and 2009

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 14 of 24

Roche Diagnostics believes that including or excluding specific counties, zip codes, etc. will be extremely confusing to beneficiaries who are accustomed to obtaining their diabetes supplies at their local pharmacies.

c. Nationwide or Regional Mail Order Competitive Bidding

Competitive Bidding Must Ensure Competitiveness, Access to Quality Products, and Reasonable Utilization

Roche Diagnostics has a number of concerns surrounding the implementation of a national or regional mail order program for diabetes supplies. Today, 60% of Medicare beneficiaries obtain their supplies at retail outlets. There are a number of reasons for this which we have described in detail to CMS in our comments on the Quality Standards. They include convenience and the training and support that beneficiaries can receive during face to face meetings with the pharmacist. These services are important in managing diabetes and are especially needed by the increased numbers of beneficiaries in the Medicare population who have cognitive disorders, are poorly educated, speak English as a second language, or have low incomes.

In section E. Criteria for Item Selection in its Proposed Rule, CMS recognizes that "...a relatively large number of suppliers...would likely increase the degree of competition...and increase the probability that suppliers would compete on quality for business and market share." We agree with this statement. Forcing beneficiaries into national mail order will create a noncompetitive market unless another viable competitive market exists. We strongly believe for the many reasons given throughout our comments on the Proposed Rule that this alternative market is retail. CMS should support a retail market by establishing pricing strategies similar to the Agency initiative that recognizes the inherent differences in the acquisition costs of drugs between retail pharmacies and national mail order suppliers. In this regard, retail pricing information would be extremely helpful. Preservation of competition will ensure that Medicare beneficiaries can choose which product delivery system is best for them and with which they are the most comfortable. Ultimately, this choice will directly impact the testing compliance regimen of many beneficiaries, the first line of defense in preventing costly and devastating complications.

Before proceeding with a mail order strategy of any significant scale for diabetes supplies, CMS must thoroughly understand this market and the types of products and services that would be available under competitive bidding.

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 15 of 24

E. Criteria for Item and Service Selection

CMS Should Exclude or Limit Competitive Bidding for Diabetes Supplies and Seek Retail Pricing Information

Because the number of beneficiaries affected, distribution chains, and training and support services associated with diabetes care systems are so radically different from other types of DME and because diabetes products were not competitively bid via a demonstration project, we recommend that they be excluded from the 2007 program until the Agency gains further experience with more standard types of DME. If the Agency does decide to competitively bid diabetes products in 2007, the affected area should be reasonably small in terms of the number of beneficiaries affected. This will minimize disruption due to product switching and retraining needs.

We agree with the methodology that CMS proposes for product categories. As mentioned earlier and from our own experience, we also agree with CMS' position that a large number of suppliers is usually indicative of a robust market that competes on quality and market share. With this in mind, we recommend that CMS actively seek retail pricing information for diabetes care supplies to determine if payment adjustments are warranted.

F. Submission of Bids under the Competitive Bidding Program

4. Bidding Requirements

d. Capped Rental Items

Roche Diagnostics supports the CMS proposal that would require the bid price of DMEPOS items to be calculated as a monthly rental single payment amount. Allowing suppliers to submit bids in this manner simplifies the bid calculation process, reducing costs to suppliers and therefore reducing bid amounts. This reduction in bid amount obviously will increase savings to Medicare.

Nonetheless, Roche Diagnostics is concerned by the specified percentages of the purchase price proposed by CMS to serve as rental payments. Roche Diagnostics believes these dramatic reductions will drive suppliers from the market, and create shortages for the products. As noted previously, there are only four major suppliers of insulin pump systems – too few to derive the level of savings that warrant competitive bidding. Moreover, with so small a universe

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 16 of 24

of suppliers, CMS will be unable to implement a competitive bidding program that ensures an adequate supply for beneficiaries, as the statute requires. In all, CMS' approach is not market bidding, but price setting, and that approach does not guarantee an adequate supply for beneficiaries.

G. Conditions for Awarding Contracts

1. Quality Standards and Accreditation

Competitive Bidding Participants Must Comply with the Quality Standards and Be Accredited

A competitive bidding program involving diabetes care supplies should not be initiated until the Quality Standards are in place and there is a mechanism through the accrediting organizations to actively enforce these standards. In our comments to the Agency on the Quality Standards, we emphasized the need to protect beneficiaries from counterfeit, adulterated or substitute products, ensure the continuation of reliable 24-hour support services, properly educate and train, minimize disruption, and supply the beneficiary with a quality product that meets his or her needs. In the case of diabetes, tens of thousands of beneficiaries could be negatively impacted by only one unscrupulous supplier. There should be no grace period for accreditation of diabetes care suppliers. Instead, sufficient time should be given for suppliers to comply with the standards and receive accreditation before they are eligible to participate in a competitive bidding program.

3. Financial Standards

The Instructions for the Financial Standards Should be Explicit and the Paperwork Burden Minimized

CMS should give attention to the reducing the paperwork burden associated with the financial standards to the extent possible because they can be particularly onerous for small mail order and independent pharmacies as well as independent pharmacies within large chains. With regard to the latter, CMS should issue explicit instructions on the information that will be needed from both the parent company and its subsidiaries.

4. Evaluation of Bids

a. Market Demands and Supplier Capacity

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 17 of 24

The Unique Factors Surrounding Diabetes Care Should be Addressed in Determining Supplier Capacity

CMS should ensure that the rising prevalence of diabetes is taken into account when determining supplier capacity. An increase in utilization may also potentially be found with mail order and we recommend that the Agency study this phenomenon prior to implementing mail order on a large scale. As CMS is aware, the service demands for blood glucose test systems are relatively small when compared to other DME, although the need for 24/7 support services is high. The need for beneficiary retraining and education will be quite significant and will have a large impact on pharmacies and mail order firms. The issue of switching out product, retraining and education for beneficiaries with diabetes in determining supplier capacity in addition to enhanced support services should be added as a major provision in the next issuance of the regulation.

b. Composite Bids

CMS Should Use the Polk County Methodology for Determining Composite Bids

Roche Diagnostics believes that the use of composite bids will create the incentive to provide aberrant pricing in order to produce a good composite score. CMS should use the approach taken in Polk County to determine the composite bid because this approach has been successfully demonstrated. The Agency always has the opportunity to modify the methodology in the future.

c. Determine the Pivotal Bid

To Prevent Disruption, CMS Should Use the Median Bid for Diabetes Supplies

Beneficiary access to quality products with minimal disruption should be of primary concern to CMS in selecting a methodology for determining the pivotal bid for diabetes supplies. While achieving targeted savings, the Agency should focus on maximizing the number of suppliers available. CMS should use the median bid for diabetes supplies because this will ensure that a greater number of suppliers are selected. This will lessen the burden of switching out product, retraining and education. It will ensure that convenient access for beneficiaries is maintained. Because the need to supply high quality products that meet the unique needs of the beneficiary are so great in addition to the capacity needed to provide education and assistance, Roche Diagnostics believes that CMS should

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 18 of 24

evaluate the compliance of all eligible bidders with the Quality and Financial Standards in conjunction with bid submissions.

d. Assurance of Savings

CMS Should Use the Total Cost of the Product Category

CMS should use the approach taken in Polk County to achieve savings because this method has been successfully demonstrated. It allows suppliers some flexibility which may be important in establishing a new business model and as long as overall cost savings for the entire product category are achieved, it should not matter if the cost of one item increases. The Agency has the opportunity to modify this approach in the future.

H. Determining Single Payment Amounts for Individual Items

1. Setting Payment Amounts for Individual Items

CMS Should Use an Adjustment Factor

In determining the payment amount for individual diabetes supplies, we recommend that CMS use an adjustment factor in order to discount low bids. This methodology was used successfully in Polk County and will be of benefit to small pharmacies and mail order companies.

2. Rebate Program

A Rebate Program Raises Serious Legal Concerns

The proposal of suppliers offering rebates to beneficiaries raises a number of serious issues that CMS should consider in its next issuance of the competitive bidding rule. We believe that the Agency must address the following questions:

- Is this inducement?
- How can contract suppliers take advantage of a rebate program if they cannot advertise either directly or indirectly to beneficiaries?
- Does CMS have the resources to implement the very aggressive oversight that will be needed to audit a rebate program and to address the enormous potential for fraud and abuse?

I. Terms of Contracts

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 19 of 24

5. Furnishing Items and Services to Beneficiaries who's Permanent Residence is Within a CBA

CMS Must Ensure that Beneficiaries Can Easily Obtain Diabetes Testing Supplies

Beneficiaries with diabetes from a noncompetitively bid area must be assured of having a complete and updated list of all Medicare contract suppliers and their exact location in order to ensure access to needed supplies when in a competitively bid area. It is also important that this information include those suppliers who can provide items in an emergency situation. A complete list of the individual products offered by each contract supplier should be provided in order for beneficiaries to determine if that supplier carries the items that match the blood glucose test system that he or she is using.

K. Opportunity for Participation by Small Suppliers

The Impact of the Competitive Bidding on Small Suppliers of Diabetes Care Products Needs to be Further Investigated

In this section as well as throughout this Proposed Rule, it is clear that CMS is thinking primarily of typical DME suppliers and not suppliers of diabetes care items. It also does not appear that CMS has directed RTI to conduct a focus group with small suppliers of diabetes care products. We believe that most of these small suppliers will be at an extreme disadvantage in complying with many aspects of the Quality Standards and with this rule as presently proposed and as noted in our comments to the Agency. If RTI has not convened a focus group of small diabetes care suppliers, we recommend that it do so prior to issuance of the next rule and the Quality Standards.

L. Opportunity for Networks

Roche Diagnostics does not support the formation of networks due to the anticompetitive nature of this type of business model. We do not understand how this is not considered collusion as stated in the Proposed Rule in section N., Monitoring and Complaint Services.

M. Education and Outreach

Detailed Guidance Must be Given to Beneficiaries and Providers on Product Switching, Education and Retraining Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 20 of 24

We are extremely pleased that CMS will be establishing a competitive bidding education and outreach program. As the Agency is well aware, there will most likely be tens of thousands of beneficiaries with diabetes in the selected MSAs who will need to understand the changes that will be made. Just as important will be much needed guidance on the process for product switching and the intended plans for beneficiary education and retraining. CMS may want to consider a phased-in approach to switching and retraining so that providers and suppliers are not overly burdened with these duties. Special attention may have to be given to inner city, minorities and low income populations who are often in walking distance or a short bus ride to their customary supplier and who may be more difficult to contact than the population at large. We also think that providers - physicians, pharmacists and diabetes nurse educators - who have patients in the competitive bidding area will need education. Many providers prescribe diabetes care systems based on advanced features including IT connectivity and the ability to load patient results into a clinical evaluation program that is housed in the physician's office. Under competitive bidding, it is likely that these features will not be available on the products that will be selected. Pharmacists, if they can no longer provide diabetes supplies to their customers, should have information in order to guide the beneficiary to a new supplier.

Selection of a Product or Supplier in a Competitive Bidding Area Does not Confer Lower Quality to Non Selected Products and Suppliers

In this section, CMS states that one of the benefits conferred by competitive bidding is that beneficiaries will be told that they are receiving higher quality products. We strongly disagree with this statement and firmly believe that the opposite will be true. This type of inference will be extremely detrimental to products and suppliers of products that are not selected for competitive bidding solely based on price or ability to provide the item in sufficient quantities - not on the quality of the products or the ability to comply with the Quality Standards. This statement should not be considered as a strategy to promote the competitive bidding program to Medicare beneficiaries.

N. Monitoring and Complaint Services for the Competitive Bidding Program

CMS Must Aggressively Monitor the CB Program

We strongly support all CMS efforts to detect any abuses that occur under competitive bidding. Due to the serious medical outcomes resulting from failure

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 21 of 24

to appropriately monitor blood glucose levels, we urge the Agency to be especially aggressive and timely in its oversight. As mentioned previously in these comments, there is the potential for only one supplier to harm thousands of beneficiaries. We also recommend that in instances where a breach of quality has been identified, that the affected beneficiaries be notified immediately so corrective action can be taken.

O. Physician Education and Outreach

Supplying all Brands within a HCPCS Code will Lessen the Burden of Mass Switching

In our comments to the Agency on the Quality Standards, Roche Diagnostics included a list of blood glucose system features beyond what was recommended in the standards. These features, listed below, should be made available by suppliers who are selected to participate in the competitive bidding area.

- Diabetes information management capabilities such as connectivity/downloading, memory, averaging, user prompts, etc.
- Ability to compensate for reduced cognition or physical impairments such as vision loss, poor dexterity, compromised motor skills, thinning of the skin at lancing sites, etc., and
- Products that provide more accurate results by accounting for anomalies caused by hematocrit, medications, humidity, temperature, etc.

We recommend that CMS require these features as a basis for product selection because they will cover the vast majority of clinical needs and desired characteristics. We also wonder if information from the Polk County and San Antonio demonstration projects could be used to inform CMS in a timelier manner as to whether all brands within a HCPCS code should be supplied. We believe that this may be a much more preferable option in that it will resolve many access issues and prevent the need to switch out products and educate and retrain the thousands of beneficiaries with diabetes.

R. Establishing Payment Amounts for New DMEPOS Items

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 22 of 24

Payment Amounts for New DMEPOS Should be Issued as a Separate Regulation

This is an extremely important proposal that is not related to the <u>implementation</u> of the competitive bidding program. Roche Diagnostics does not believe that it should be included in the Proposed Rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

CMS Should not Combine Coverage, Coding and Payment Decisions
In this provision CMS appears to be combining coverage, coding and payment decisions. This is not appropriate. In addition, we find that not enough information has been given regarding the specific methodologies that will be used to perform the functional and the medical benefits assessments. These should be made available for public comment. For some new products, a medical benefits assessment can be difficult if not impossible to perform if there is not enough scientific literature available. We also note that the Food and Drug Administration is charged with determining the safety and effectiveness of medical products. Thus, CMS' proposal to evaluate these criteria is in conflict with regulatory simplification measures.

V. Regulatory Impact Analysis

B. Anticipated Effects

CMS Should Establish a More Realistic Timeline for Program Implementation

CMS proposes to conduct the first round of competitive bidding in 2006 with the program taking effect in 2007. We think that this timeline cannot accommodate the finalization of the Quality Standards, issuance of the Proposed Rule on accrediting agencies, selection of accrediting agencies, finalization of the competitive bidding regulations, issuance of an RFB and holding a bidder's conference. We are very concerned about this aggressive approach because to date, we do not believe that the Agency has adequately addressed the issues associated with diabetes care in the draft Quality Standards or in this Proposed Rule.

UMRA Applies to the Competitive Bidding Rule

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 23 of 24

Roche Diagnostics disagrees with the Agency's assertion that the Unfunded Mandates Reform Act does not apply to competitive bidding rule. In order to participate in the Medicare program at all, suppliers are forced to bid in the program.

D. Program Savings

The Medicare Advantage Plans are modeled after the commercial plan market. Many of these plans utilize various cost controls for diabetes supplies similar to the Part D benefit, including formularies and co-pays. As a result, we do not think that CMS should assume additional savings from these programs.

E. Effect on Beneficiaries

The Effect of Competitive Bidding on Beneficiaries with Diabetes Has Not Been Adequately Assessed

Diabetes care supplies are obtained in an entirely different manner than other DME products. Thousands of beneficiaries – a significantly higher population with respect to the number of beneficiaries receiving an individual DME product - will be affected by competitive bidding implementation. Many will have to change suppliers. It is likely that tens of thousands will have to switch products and be retrained. Diabetes care supplies do not meet the criteria for grandfathering. They were not included in either of the two demonstration projects. For all of these reasons, we believe that CMS has failed to demonstrate the impact that competitive bidding will have on beneficiaries with diabetes.

F. Effect on Suppliers

- 1. Affected Suppliers
- 2. Small Suppliers

CMS Should Not Base Assumptions on the Demonstration Projects In the Proposed Rule, CMS has indicated that it would like to change the methodologies that were used in the demonstration projects. We question, therefore, the assumption that 50% of suppliers will be awarded contracts. It is also incorrect to assume that a diabetes supplier such as a retail pharmacy receives 50% of its revenue from Medicare.

Hon. Mark B. McClellan, M.D., PhD June 28, 2006 Page 24 of 24

Thank you for considering our comments. Should you have any questions or require additional information, please contact me.

Respectfully submitted,

Dee Simons

Director Public Health Policy

Roche Diagnostics



Mr. Herb Kuhn Centers for Medicare and Medicaid Services 7500 Security Boulevard Mail Stop C5-08-27 Baltimore, MD 21244-1850

Re: <u>Comments on Draft of Proposed Recommendations on Quality Standards</u> for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Dear Mr. Kuhn:

Roche Diagnostics is pleased to submit comments on the draft Quality Standards for DMEPOS and Other Items and Services. Our company is proud to be one of the leading manufacturers of diabetes care systems. We have been developing these technologies for almost thirty years. During that time, diabetes care systems, consisting of the meter, strip, lancet device, lancet and control solutions have been vastly improved. The initial large, cumbersome, inaccurate and painful systems from 30 years ago have evolved into user friendly ones that are compact, light, accurate and less painful. Data downloads from these systems identify trends for a number of blood glucose parameters. Providers and patients use this information to adjust treatment plans involving diet, exercise, insulin and other medications, as well as to evaluate the efficacy of treatment and educational programs. These connectivity features are becoming increasingly important as we foster disease management programs and move toward a national heath information technology infrastructure.

Many of the technological improvements such as not having to handle individual strips or lancets, simpler maintenance, alternate site testing, easier blood collection, smaller sample sizes, ability to adjust puncture depth and larger readout displays can make a vast improvement in the health and quality of life for a Medicare beneficiaries. These technological advances result in increased testing compliance with an accompanying decrease in the devastating and costly complications of diabetes. The development of each one of these features has required years of research and work, involving many consumers, scientists and other experts in the fields of clinical and market research, software development, engineering, biochemistry, and ergonomics.

Mr. Herb Kuhn November 23, 2005 Page 2 of 18

In reviewing the draft of the Quality Standards, our first impression is that the document, for the most part, appears to be written for the "standard" DME supplier, not for retail pharmacy chains or firms that supply diabetes care systems via mail order. We also note that the standards do not reflect — or perhaps more importantly — do not take advantage of current standard practices in diabetes care that are more efficient, safer and of higher quality than those proposed in this draft document.

Last, we wish to point out that the operation, features and differences in the components of diabetes care systems can be quite significant - not only between brands but within the same product line. This is not acknowledged in the standards and is, in fact, marginalized. Roche believes that this is dangerously misleading considering the vulnerability of the affected population.

One example in the document that encapsulates many of the above observations is the requirement that the supplier – in this case most likely a retail pharmacist – train beneficiaries on diabetes care systems and provide a 24-hour assistance program. It is Roche's view that this is not practical, feasible, safe or efficient. We elaborate on these points further in the body of our comments.

General Recommendations

Consult with diabetes care providers.

The list of contributors for first draft of the Quality Standards did not include individuals or organizations that provide health care services to beneficiaries with diabetes. The proposed standards suffer because of this oversight by attempting to create a new system that will be at best extremely disruptive, if not detrimental, to beneficiary well being. Due to the unique interactive nature of diabetes care systems with the patient, we believe that CMS should seek input from the American Diabetes Association, American Association of Clinical Endocrinologists, American Association of Diabetes Educators, National Association of Chain Drug Stores and National Association of Community Pharmacies as it revises the Quality Standards. By obtaining this counsel, CMS can build and improve upon current practices.

Consult with suppliers of diabetes care products.

Roche has also observed that the contributors to the draft Quality Standards included Internet and mail order pharmacies, but not retail suppliers, the predominant choice for seniors when obtaining their diabetes care products. It

Mr. Herb Kuhn November 23, 2005 Page 3 of 18

is worth noting that these retail suppliers not only include drugstores such as CVS® and Rite Aid® but pharmacies in large chain grocery stores and large retail chains such as WalMart®. Thus, these standards have considerable potential to affect thousands of retail suppliers throughout the U.S and millions of Medicare beneficiaries.

We believe that it is critical that CMS seek input from The National Association of Chain Drug Stores and the National Association of Community Pharmacies. These groups can inform CMS about the demographics and needs of its purchasers in addition to the role that the pharmacist plays in the day-to-day management of beneficiaries with diabetes and how this role is significantly different from "standard" DME suppliers. We are particularly concerned that some of the requirements in the draft Quality Standards may prove to be overly burdensome for small suppliers – both independent pharmacies and mail order providers. Other requirements, however, may prove very costly if applied to a large supplier base.

Incorporate the "Standards of Medical Care in Diabetes."

The American Diabetes Association's "Standards of Medical Care in Diabetes" is an excellent resource on information about diabetes care with specific sections addressing the team of health care providers needed to properly educate, manage and treat a patient with diabetes, self-monitoring of blood glucose, and diabetes care for the elderly. We recommend that CMS refer to these and incorporate the ADA standards into the Quality Standards for diabetes care systems where appropriate. We are including a copy of these standards with our comments for your reference.

Harmonize the Draft Quality Supplier Standards with the Diabetes Education and Training Quality Standards.

The Balanced Budget Act of 1997 expanded Medicare coverage for diabetes outpatient self-management training. This resulted in the issuance of 42 CFR Parts 410, 414, 424, 480, effective February 27, 2001, which delineate the standards that should be met for this training in order for the provider to receive Medicare payment. The proposed Quality Standards for Suppliers fails to address how compliance with the 2001 regulation would alter supplier compliance as stated in the proposed Quality Standards. For instance, if a beneficiary receives training on the operation and use of a diabetes care system administered through an entity that meets the requirements under 42 CFR Part 410, it would not be necessary for the supplier to repeat this training.

Mr. Herb Kuhn November 23, 2005 Page 4 of 18

Beneficiary health outcomes must be measured.

CMS has stated that one of the goals of the Quality Standards is to improve beneficiary outcomes. Roche agrees and recommends that CMS issue its plan for how it will demonstrate the effect that the competitive bidding Quality Standards will have on the health of beneficiaries with diabetes. We believe that these measures should be of appropriate scientific rigor to demonstrate accurately whether the quality of care has been diminished or enhanced through evaluation of endpoints such as outpatient, inpatient and long term care costs and an increase or decrease in diabetes comorbidities such as vision loss, amputation, and renal disease.

Develop separate administrative standards for diabetes care systems.

Due to the extreme differences between "standard" DME suppliers and their distribution chains and those that exist for diabetes care systems, we recommend that separate administrative standards be drafted for suppliers of diabetes care systems.

Specific Comments

Section 1: Supplier Business Quality Standards

Administration

3. Procurement and testing of quality DME, first bullet. Diabetes care products are cleared or approved for marketing by the Food and Drug Administration. Most large manufacturers are ISO certified. As such, the manufacturer supplies the FDA with substantial documentation regarding product quality and safety. Some of this information is proprietary in nature and thus protected. It is unclear to Roche as to why a retail supplier would need this same information, or for that matter, be able to make sense of it. Moreover, the proprietary nature of this information would make manufacturers exceedingly reluctant to submit it to a supplier unless appropriate legal safeguards were in place. We suggest that for diabetes care systems, CMS defer to FDA cleared or approved products.

Roche strongly recommends that due to the significant problems with the sale of counterfeit, diverted or otherwise misbranded diabetes products, CMS require suppliers to provide only FDA approved products and packaging that are either

Mr. Herb Kuhn November 23, 2005 Page 5 of 18

directly procured from the manufacturer or a distributor whose sole source of product is directly from the manufacturer.

- 4. Delivery of quality services to beneficiaries, first bullet. Roche recommends that CMS further clarify the policies and procedures that define the scope and provision of supplier standards, beneficiary eligibility requirements, how services are coordinated with the treating physician and health care team, and business and emergency operating hours with regard to retail outlets and mail order firms. Because suppliers of diabetes care systems differ significantly from other DME suppliers, we believe that CMS should consider developing separate standards for the former. Moreover, these provisions, when applied to retail and mail order firms have strong potential to be overly burdensome. We suggest that CMS learn more about the interactions of the diabetes health care team with the supplier and the interactions the supplier has with the diabetes care system manufacturer by consulting with the appropriate organizations.
- 4. <u>Delivery of quality services to beneficiaries, second bullet</u>. Again, we must underscore the unique differences between the supply of diabetes care systems and other types of DME and emphasize the need for standards that are more applicable to the former... The requirement "Ensures that mail order services are not used for the initial delivery, set-up and beneficiary education/training for certain DME equipment and supplies" establishes a clear inconsistency in the way that the standards are applied to mail order suppliers and pharmacies. One is required to train beneficiaries and one is not. Moreover, the proposed standards are silent as to how the training will be accomplished in the latter instance.

Roche notes that under 42 CFR Part 410, the beneficiary is entitled to training in the management of diabetes, including the use diabetes care systems. The choice of who performs this training is left to the discretion of the provider. The Quality Standards, however, state that the supplier must perform training. In order to avoid significant confusion in the provider and supplier communities concerning these requirements, the Quality Standards must clarify in what instances training should be performed by a supplier.

We recommend that face-to-face training be required for the initial use of a new diabetes care system and that the training be performed by an appropriately credentialed individual. Training should include the witnessing of the beneficiary's ability to correctly operate the meter, strip and lancet – all of which may differ significantly from the beneficiary's previous system. The beneficiary

Mr. Herb Kuhn November 23, 2005 Page 6 of 18

must also be able to properly interpret the results particularly with regard to pre and post prandial fluctuations which occur due to diet, exercise and stress. (Bergenstal 2005). Most suppliers cannot be held responsible for performing this type of training for reasons given later in our comments.

- 5. <u>The supplier shall:</u>, third bullet, item c). Roche agrees that each supplier location should meet the quality standards and be accredited. We note, however, that accrediting agencies will face a formidable task in accrediting and monitoring large retail suppliers having hundreds of locations in many MSAs. In addition, the overall burden of compliance with the standards will be enormous for national retailers with thousands of outlets. Roche recommends that CMS consult with large retail suppliers and potential accrediting agencies to see if there is a way to streamline compliance procedures.
- 6. <u>The supplier shall develop and implement a compliance plan...</u> Roche notes that it is likely that small independent pharmacies, some regional pharmacies and small mail order firms will not have enough resources to meet these standards. We recommend that CMS consult with the appropriate organizations to determine the effect that these requirements will have on small businesses.

Financial Management

- 1. A financial management plan... and, 2. Financial statements... Small independent pharmacies and small mail order companies may have difficulty meeting these requirements. CMS should consult with these suppliers. We also recommend that CMS seek guidance regarding how individual pharmacies within a large chain and foreign owned subsidiaries can meet these standards most effectively. Perhaps the financial information from the parent company would be most suitable in these instances.
- 3. Notification to CMS and the accreditation organization... CMS needs to state the criteria that define "potential adverse financial conditions." We suggest that the Agency work with diabetes care suppliers to clarify how this would apply to large chains and small independents.

Mr. Herb Kuhn November 23, 2005 Page 7 of 18

Human Resource Management

- 1. The supplier shall obtain criminal background checks... When considering all of the types of retail outlets that could receive a competitive bidding award, Roche notes that the number of criminal checks necessary could number in the many thousands. The resource burden is enormous. We recommend that CMS solicit input from retail and mail order suppliers to determine the necessity of this requirement.
- 2. The supplier shall have sufficient full-time and part-time personnel to provide the services..., and 4. The supplier shall have and implement an assessment program... Roche believes that the overall burden for implementing these requirements in the current retail distribution chain is enormous. Small independent pharmacies and mail order firms may not be able to comply with these standards. It is also unclear if the competency requirements for the supplier in this case a retail pharmacist or a lay person in a mail order firm would need to meet the qualifications of a certified diabetes educator. We recommend that CMS consider developing a standard that is specific to diabetes care systems and consult with the appropriate pharmacy and mail order organizations.

Beneficiary Services

- 1. The supplier shall process...Roche recommends that the supplier be required to document and inform both the provider and beneficiary of the reason for a change or deviation from the original item ordered to what was actually dispensed. This may help to reduce product switching.
- 2. The supplier shall ensure..., first bullet. Roche believes that suppliers should clearly designate in any advertising or outreach to providers and patients which products are available to Medicare beneficiaries and which products are not available.
- 3. The supplier shall ensure..., third bullet. Roche does not believe that most of this information is critical to obtaining diabetes care systems. It will unnecessarily result in a massive recordkeeping burden on both the providers and the suppliers. In addition, we question whether privacy laws and regulations would allow for the sharing of superfluous patient information. Last, we wonder if the supplier will be able to determine from this information whether the

Mr. Herb Kuhn November 23, 2005 Page 8 of 18

correct diabetes care system has been selected by the provider. We recommend that CMS consult with provider and supplier groups to determine the standards that are needed specific to diabetes systems and to determine the state of current practice in this area.

Performance Management

- 1. The supplier shall provide evidence... We believe that much more detail is needed here and that it be made more applicable to the suppliers of diabetes care systems. Roche strongly recommends that CMS confer with the appropriate supplier groups to determine how this can be implemented for small retail/mail order suppliers and individual pharmacies within a chain.
- 2. The supplier shall identify... Roche is extremely concerned about this provision. FDA regulations mandate that the manufacturer evaluate product complaints and inform the Agency via the Medical Device Reporting regulations (21 CFR 820.198 and CFR 803) in cases where problems are considered to be "reportable" events. These regulations are in place to protect the public health. The CMS requirement for suppliers to investigate root causes makes little sense because the supplier cannot possibly perform this function. Of equal importance is that in this proposed scenario the manufacturer may never even know about the event and be able to address it, report to FDA, or take corrective action if needed. Thus, this provision has the potential to endanger the public health. Roche strongly recommends that CMS require suppliers to report problems including any adverse effects of the equipment and supplies, to the manufacturer of those products.
- 3., 4., 5., 6. The supplier's performance management system... In many instances, these requirements do not appear to be easily adapted or applicable to retail situations. Due to the enormous resource burden that this will place on the suppliers in addition to the apparent lack of applicability, Roche recommends that CMS, after consultation with the appropriate supplier groups, issue a revised standard for diabetes care products that is more appropriate for the retail environment.

Mr. Herb Kuhn November 23, 2005 Page 9 of 18

Equipment and Safety

- 1. The supplier shall maintain... To the best of our knowledge, the supplier does not track the batch numbers for diabetes care supplies. The manufacturer maintains batch numbers.
- 2., 3., 6. The DME supplier shall implement... These do not pertain to diabetes care suppliers; therefore, they should be specifically excluded from this requirement.

Beneficiary Right and Ethics

1. Suggested additions.

- For diabetes care equipment, the specific brand and model numbers offered by the supplier.
- Explanation as to why a product is no longer offered or not available.
- Availability of diabetes care systems not offered under competitive bidding and how they can be obtained if desired.
- 1. Policies for after-hour and emergency coverage, fifth bullet. This is an extremely important requirement for Medicare beneficiaries with diabetes. As a manufacturer of diabetes care equipment and supplies, Roche operates a multilingual (186 languages) assistance service dedicated to our ACCU-CHEK® product line. This live service is manned around the clock 365 days per year. We average almost 1.4 million calls annually. About half of these are from individuals who are 65 years of age or older. It is very likely that other leading manufacturers have similar services and numbers of inquiries. We believe that for diabetes care systems, a standard based on anything less than an in-depth knowledge of the diabetes care system and live 24/7/365 support is not adequate. These elements are critical to the care of a population known to have significant comorbidities, increased cognitive problems and limited literacy.

Information Management

- 8. The supplier's marketing materials... We recommend that CMS adopt a marketing approval process for suppliers similar to the Agency's Medicare Part D approval process. Without such an approach, we do not see how this can be enforced.
- 8. Forms for beneficiaries..., last bullet. Since many seniors do not have access to the Internet, Roche recommends that the Quality Standards require suppliers to make forms available by additional means.

Section 2: Appendices for Supplier Product-Specific Service Requirements

Appendix A: Supplier Product-Specific Service Requirements

Inspection and Preparation

Diabetes care supplies are received by the supplier prepackaged, making it impossible for the pharmacy or mail order firm to ensure the safety or functionality of the product. Were suppliers to actually open the packaging for purposes of ensuring safety and functionality, this would have significant implications under the Food, Drug and Cosmetic Act and related regulations. Indeed, it could have a tremendous impact on patient safety. Proper storage (temperature and light), tampering and counterfeiting should be addressed in the standards. We are not aware of instances where the supplier would actually attempt to adjust or replace parts.

It is usually the physician or the diabetes educator who recommends which product is appropriate for the patient, not the supplier. Roche agrees that it is important for the pharmacist to be aware of changes in patient status. The proposed Service Plan, however, can only be applied to typical DME suppliers. It cannot be applied to retail pharmacies who may see hundreds of patients in a year or to mail order suppliers who do not see patients at all. We recommend that the appropriate provider and supplier groups be consulted to determine what the requirements, if any, should be established for diabetes care suppliers.

Delivery and Setup

Mr. Herb Kuhn November 23, 2005 Page 11 of 18

This section is not applicable to diabetes care supplies and should be so stated.

Training/Instruction to Beneficiary and Caregiver

Training in the use of diabetes care supplies is a cornerstone to the successful management of diabetes. The ability to effectively use diabetes care systems is directly related to the quality of training received and the capabilities of the individual beneficiary. Because of this, a blanket requirement that the pharmacist/supplier perform all training is ill conceived. Roche also notes that requiring a pharmacy to provide instructions for use could have implications under the FDCA. The package insert for blood glucose meters, which is governed as labeling under the auspices of FDA, contains the instructions for use. These are provided by the manufacturer, not the supplier.

Training for those who are newly diagnosed and training on new systems for beneficiaries with reduced cognition, limited literacy or certain physical impairments should be given face-to-face by a diabetes educator or similarly qualified health care professional. Mail order suppliers will not be able to perform this type of training. For those beneficiaries who are well experienced in the management of diabetes, training may not be necessary at all, while others may only need an overview of the basic operations of the diabetes care system. In the former instance, required supplier training would squander significant Instruction sheets/videos and manuals may be appropriate for resources. beneficiaries experienced in diabetes management but should not be considered as a replacement for appropriate training and education of Medicare beneficiaries who are newly diagnosed, learning impaired or who are otherwise unable to benefit with these learning tools. In all cases the supplier should require attestation that the beneficiary/caregiver has successfully completed training via a Medicare-approved diabetes self-management training course or during the course of, or incident to, a physician or other qualified health care provider service.

CMS must ensure that beneficiaries receive the training that is necessary to meet their individual needs. Patients are often unaware of actions they should take in response to their blood glucose results (Bergenstal 2005). While most pharmacists are an excellent resource to reinforce the basic operations of the equipment, they cannot be expected to possess an in depth knowledge of multiple product lines and differing features to the extent needed to properly perform the training of hundreds of beneficiaries a year, many of whom have

Mr. Herb Kuhn November 23, 2005 Page 12 of 18

reduced cognition and limited literacy. Pharmacists also cannot be expected to be able to integrate that training into the complex management necessary to achieve glycemic control.

In its Standards of Medical Care for Diabetes, the American Diabetes Association states:

"Because the accuracy of SMBG [self-monitoring blood glucose] is instrument- and user-dependent, it is important for health care providers to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. In addition, proper use of SMBG requires proper interpretation of the data. Patients should be taught how to use the data to adjust food intake, exercise, or pharmacological therapy to achieve specific glycemic goals. Health professionals should evaluate at regular intervals the patient's ability to use SMBG data to guide treatment." (Diabetes Care, 2005).

Roche believes that many in the Medicare population will require more than a basic tutorial on how to operate a diabetes care system. As CMS is well aware, Medicare beneficiaries include a high share of individuals with functional and cognitive impairments. (Kaiser Foundation 2005). Further, reduced cognitive function is linked to diabetes. (Brands, 2005; Cox, 2005; Ferguson 2005; ADA Standards – Diabetes Care, 2005). Limited literacy is also characteristic of the Medicare population. Approximately 44% of adults age 65 or over have limited reading skills, 38% of Medicare beneficiaries have not completed high school and 23% have less than 9 years of education. (Goldstein, 2001). The following are identified risk factors pertinent to the Medicare population that are associated with limited literacy (IOM 2004; Weiss, 2003):

- Advanced age (≥ 65 years)
- Limited formal education (less than high school)
- Poverty or limited income
- Presence of chronic disease
- Medicare/Medicaid beneficiary
- Ethnic or minority group

The impact of limited literacy on health is well documented. Limited literacy results in:

Mr. Herb Kuhn November 23, 2005 Page 13 of 18

- <u>Higher hospitalizations</u> (Baker, Gazmararian, Williams, Scott, Parker, Green, Ren & Peel, 2002)
- Greater annual health care costs (Weiss & Palmer, 2004)
- <u>Poorer management and knowledge of chronic disease</u> (Schillinger, Grumbach, Piette, Wang, Osmond, Daher, et. Al., 2002; Williams, Baker, Honig, Lee, Nowlan, 1998; Williams, Baker, Parker, Nurss, 1998))
- <u>Underuse of preventive health services</u> (Scott, Gazmararian, Williams, Baker, 2002)

Roche believes that it is imperative that the Quality Standards take the above findings and their implications into account when considering education and training for Medicare beneficiaries with diabetes. If the physical, cognitive and literacy limitations of this population are ignored, beneficiaries will suffer harm and the costs associated with the treatment of diabetes complications will rise.

We recommend that in lieu of a blanket requirement for supplier training, CMS build upon the education and training systems already in place by seeking advice from the appropriate professional and supplier organizations, reviewing 42 CFR Parts 410-498 and the ADA Standards.

Roche also notes that presently, after hours support is most often performed by the product manufacturer. While a 24-hour pharmacy could offer such a service, it is likely that it will not be able to field most questions and will not have the in depth experience needed in order to be effective with the Medicare population.

Follow-up

Roche recommends that this section not be applied to diabetes care suppliers and to consult with provider and supplier organizations to determine appropriate standards, if any.

Appendix H: Diabetic Equipment and Supplies

Inspection and Preparation

General Product-Specific Service Requirements section.

Please refer to our previous comments. In addition, we recommend that the following be added:

Mr. Herb Kuhn November 23, 2005 Page 14 of 18

"Suppliers must provide products that meet individual beneficiary needs. The range of products should include the following features:

- Diabetes management capabilities such as connectivity/downloading, memory, averaging, user prompts, etc.;
- Ability to compensate for reduced cognition or physical impairments such as vision loss, poor dexterity, compromised motor skills, thinning of the skin at lancing sites, etc.; and
- Products that provide more accurate results by accounting for anomalies caused by hematocrit, medications, humidity, temperature range, etc."

Equipment Management

General Product-Specific Service Requirements section. Please refer to our previous comments.

Amend the bulleted sentence as follows: "Furnish a home blood glucose monitor that is appropriate for any physical limitations such as visual impairment, thinning of the skin in lancing site areas, impaired cognition or dementia, limited dexterity or other factors such as pharmacologic interferences."

Delivery/Setup

General Product-Specific Service Requirements section. Please refer to our previous comments.

Add a second bullet: "Mail order suppliers shall not overly dispense products and will maintain recorded telephone logs of supply orders in addition to maintaining documentation of such orders."

Training/Instruction to Beneficiary and Caregiver(s)

General comment on this section. Again, Roche notes that suppliers cannot be expected to perform primary training on diabetes care systems for all Medicare beneficiaries. The observations for the following sections are made to provide additional information only.

Laser skin-piercing device and disposable film cartridge

Mr. Herb Kuhn November 23, 2005 Page 15 of 18

Equipment Usage

How to select..., first bullet. Delete "glucometer" in this section and in all other sections. Glucometer® is a brand name for a blood glucose monitoring system.

Home Blood Glucose Monitor

Equipment Usage

Usage is likely to vary slightly...first bullet. Roche knows that system operation and use can vary substantially - not only among products manufactured by different companies, but within an individual product line. The American Diabetes Association also recognizes that diabetes care systems are unique and are prescribed based on the patient profile. In its "Standards of Medical Care in Diabetes," the ADA states that:

"It is recognized that the use of formularies, prior authorization, and related provisions, such as competitive bidding, can manage provider practices as well as costs to the potential benefit of payors and patients. However, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action and all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic control and to reduce the risk of complications. To reach diabetes treatment goals, practitioners should have all classes of antidiabetic medications, equipment, and supplies without undue controls. Without appropriate safeguards, these controls could constitute an obstruction of effective care. (Diabetes Care 2005).

We suggest that the statement be revised to "Usage will vary among brands and brand models."

Add the following bullet: If the blood glucose monitoring system includes memory, pattern management, connectivity features, beneficiary instruction in the appropriate and successful use of these features is required.

#####

Mr. Herb Kuhn November 23, 2005 Page 16 of 18

In conclusion, Roche recognizes that developing Quality Standards for diabetes care is a difficult task made even more so because they will potentially impact the practices of thousands of suppliers and providers and the lives of millions of beneficiaries. We trust that our comments have been helpful and look forward to working with CMS to design standards that promote the health and quality of life for beneficiaries who have diabetes. Please contact us if you require additional information.

Respectfully submitted,

Dee Simons

Director Public Health Policy

Roche Diagnostics

. . .

References

American Diabetes Association. (2005). Standards of Medical Care in Diabetes. Diabetes Care, 28 (Supplement 1).

Baker, D.W., Gazmararian, J.A., Williams, M.V., Scott, T., Parker, R.M., Green, D. et al. (2002). Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. American Journal of Public Health, 92, 1278-1283.

Bergenstal, R.M., Gavin, J.R. (2005). The role of self-monitoring of blood glucose in the care of people with diabetes: report of a global consensus conference. American Journal of Medicine. 118, (9a), 15.65.

Brands, A.M.A., Biessels, G.J., DeHaan, E.H.F., Kapelle, L.J., Kessels, R.P.C. (2005). The effects of Type 1 diabetes on cognitive performance: A meta-analysis. Diabetes Care, 28 (3), 726-735.

Cox, D.J., Kovatchev, B.P., Gonder-Frederick, L.A., Summers, K.H., McCall, A., Grimm, K.J., Clarke, W.L. (2005). Relationships between hyperglycemia and cognitive performance among adults with type 1 and type 2 diabetes. Diabetes Care, 28 (1), 71-77.

Ferguson, S.C., Blane, A., Perros, P., McCrimmon, R.J., Best, J.J.K., Wardlaw, J., Deary, I.J., Frier, B.M. (2003). Cognitive ability and brain structure in Type 1 diabetes: Relationship to microangiopathy and preceding severe hypoglycemia. DIABETES, 52, 149-156.

Goldstein, E. (2001). CMS's Consumer Information Efforts. Health Care Financing Review, 23 (1), 1-4.

Institute of Medicine. Health literacy. Retrieved April 20, 2004 from http://www.iom.edu/project.asp?id=3827.

Kaiser Family Foundation. Retrieved November 3, 2005 from http://www.kff.org/

Mr. Herb Kuhn November 23, 2005 Page 18 of 18

Schillinger, D., Grumbach, K., Piette, J. Wang, F., Osmond, D., Daher, C. et al. Association of health literacy with diabetes outcomes.

*..,

Scott, T.L., Gazmararian, J.A., Williams, M.V., & Baker, D.W. (2002). Health literacy and preventive healthy care use among Medicare enrollees in a managed care organization. Medical Care, 40, 395-404.

Weiss, B.D. (2003). Health literacy: A manual for clinicians. Chicago, IL: American Medical Association Foundation.

Weiss, B.D., Palmer, R. (2004). Relationship between health care costs and very low costs and very low literacy skills in a medically needy and indigent Medicaid population. Journal of the American Board of Family Practice, 17(11), 44-47.

Enteral Nutrition Manufacturers Respiratory Care Manufacturers Wheelchair Seating Manufacturers Wound Care Manufacturers



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, Maryland 21244-1850

The Coalitions of Enteral Nutrition Manufacturers, Respiratory Care Manufacturers, Wheelchair Seating Manufacturers and Wound Care Manufacturers ("Coalitions") submit the following comments in response to the proposed rule on *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues*, 71 F.R. 25654 (May 1, 2006) (the "Proposed Rule").

The Coalitions would like to comment on the following issues:

- CMS should issue the final rule as an interim final rule with comment period
- Gap-Filling Proposal
- Criteria for Item Selection
- Exclusion of Surgical Dressings entirely from the competitive acquisition program (CAP)
- Exclusion of Enteral Nutrition from the first phase of the CAP
- Rebate Program

CMS Should Issue the Final Rule as an Interim Final Rule with Comment Period

The Coalitions have been on the record at both the PAOC meetings and the open door meeting to address the proposed rule in complimenting the CMS staff for its hard work that it has devoted to this effort. However, it occurs not only to us but also to other associations that CMS has laid out a number of unanswered questions without the Agency committing to a concrete proposal on particular topics. The product selection section of the regulation, which simply sets out general criteria for subsequent product selection, and the section regarding the application of competitively bid rates in other areas of the country, are two examples of this practice.

5225 Pooks Hill Rd. • Suite 1626 N Bethesda, MD 20814 301 530 7846 T • 301 530 7946 F marcia@nusgartconsulting.com www.nusgartconsulting.com In addition, the quality standards that are extremely relevant to the competitive bidding program have not been released yet, even though both stakeholders and CMS would benefit from comments that reflect the application of the final quality standards to this program. At the PAOC meeting, CMS staff noted that the Agency had received over 5.000 comments on the quality standards and that they had been modified. It is imperative for stakeholders to see the final quality standards since they interrelate with key elements of the proposed rule due to their impact on the type and number of suppliers who may be able to submit, bids, the size of the suppliers, the construction of product categories and the appropriateness of the approach of the proposed rule's method for determining a single payment amount.

At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS' decisions on an array of issues and thus will have an opportunity to comment on concrete proposals.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. The success of the CAP resides with defining and administering the details of the program. It is very difficult to comment if we do not know CMS' thinking on various issues which are integral to the implementation of the program.

Gap-Filling Proposal

The Coalitions commend CMS' recognition of the inadequacies of the gap-filling methodology. The gap-filling formula in antiquated and has become more problematic due to fee schedule freezes mandated by Congress. Moreover, the problem is intensified by the growing trend toward testing requirements and the SADMERC code verification of products.

CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS states that the Council on Technology and Innovation has endorsed this initiative in order to coordinate the activities of coverage, coding and payment and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

While we agree that it is important to coordinate communication of technology information among different sections of CMS and between CMS and its contractors, the administration and review of a comparative technology assessment is a comprehensive effort that raises many important procedural questions, such as:

- What would trigger such an assessment?
- Which of the three areas of the assessment would be the first area of comparison?
- Which criteria would be used for assessment in each of the three areas?
- Which entities within CMS would participate and at what level?
- What is the role of the FDA?
- When and how would outside contractors be used?
- When and how would outside stakeholder opinions be solicited?

Because of the complexity, comprehensive nature and serious implication for this type of initiative, CMS's use of the comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination, which has recently been defined in a guidance document published by the CMS Coverage and Analysis Group.

CMS also proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. The Coalitions strongly oppose this aspect of the proposal.

Since this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA, the Coalitions recommend:

- All references to the technology assessment as a part of gap filling should be removed from the final rule
- CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.
- CMS should publish this provision for comment as a separate proposed rule, with specific procedural requirements.

Criteria for Item Selection

CMS should not combine medical policies together in competitive bidding categories

The Coalitions recommend that HCPCS codes from multiple medical policies not be combined together into one competitive bidding category. We also have concerns that the proposed rule does not provide a sufficient method to evaluate whether specific medical policies and/or HCPCS codes should be included in a competitive bid.

Medical policies are created as much to categorize medical conditions and coverage as they are to categorize products and codes. For example, if competitive bidding is considered from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. Yet, from a simplistic approach it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming competitive bidding product category.

However, there are stark contrasts among the medical policies that apply to these items. In order to insure quality and access in a competitive bidding environment CMS must insure that the best providers have the opportunity to bid. Many providers structure their business around addressing specific disease states and conditions. It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or hospital bed providers, nor can the reverse be assumed.

The goal of competitive acquisition must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access. Any combination of HCPCS codes from multiple medical policies together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers, and the level of competition will be reduced. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to medical policies being combined that extend beyond their expertise and product offering.

The Sufficiency of Current HCPCS Codes for Competitive Bidding

CMS proposes to use HCPCS codes individually or grouped together in "Product Categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the proposed rule, as the Coalitions have stated previously in our October 19, 2004 CMS comments and in our November 28, 2005 quality standards comments, use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

Inappropriate code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. Some examples are:

E0277 – Powered Air Mattress E0601- CPAP

E2402- Negative Pressure Wound Therapy Pump

In each of these codes, the advanced products have different technological features that provide greater therapeutic benefits and/or support the special needs of some beneficiaries. Market utilization data from a variety of sources shows that both clinicians

and beneficiaries prefer the advanced products because of these improved patient benefits. For each of the codes listed above, the advanced products account for a majority of the Medicare Part B claims.

Because of the additional costs associated with these features, the advanced products are also at the higher end of the price range for each of these codes. Current fee schedules allow for adequate payment of the advanced products. Given the proposed bid methodology, there is a real risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code in order that they may be selected as a contracted supplier. If this occurs, there could be such significant reductions in payment that the advanced products, those preferred and used most often, will no longer be available to Medicare beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products.

In addition, certain current HCPCS codes are not appropriate for competitive bidding by code. These are codes that include within one code items of widely varying cost, technology and clinical application. Examples of these codes include support surfaces and wheelchair seating, which include within single HCPCS codes items of varying cost and complexity which are prescribed based on the patient's specific clinical condition. In the case of HCPCS codes containing items of widely varying cost, competitive bidding will not maximize program savings and will diminish beneficiary access and quality of care.

In the case of support surfaces, since the Support Surface Standards Initiative is currently devising testing for these devices, the Coalitions recommend that support surfaces cannot be effectively bid under the current HCPCS codes (which is why the Coalition of Wound Care Manufacturers is working to recommend new coding to the SADMERC) and medical policy and would request that they be excluded from competitive bidding until such time as a new coding structure and a new medical policy is implemented.

Competitive bidding of items in such codes will fail to maximize program savings because suppliers will have to include in their bids an amount reflecting the anticipated cost of the higher priced items in the code. The mix of higher and lower cost items within the code will be difficult for suppliers to accurately estimate because they do not have access to data regarding the mix in the competitive bid area; instead they only have their own mix data.

In addition, the mix may be affected in amounts that are not possible to predict due to the SSA's provision that physicians may prescribe a specific brand or mode of delivery of product within a competitively bid code. See SSA § 1847(a)(5)(a). Suppliers necessarily will be forced to add some amount of risk premium over the amounts that they would be able to bid for only the lower cost items, or for a known mix of lower and higher priced items. Program savings will be greater if higher and lower priced items currently in a single HCPCS code are separated into different HCPCS codes because these uncertainties and unknowns will be eliminated and suppliers will be able to bid their best prices for each of the lower and higher priced items.

Both of these effects can be avoided if competitive bidding is initially limited to codes that contain only homogenous, generic and clinically equivalent items. Many such codes offer significant opportunity for savings precisely because the included items are similar to each other in cost and technology. While competitive acquisition in product categories including such codes is implemented, a critical review of other codes can be conducted so that more appropriate codes can be established that do not include items of widely differing costs, technologies and clinical applications. With some of the current codes, any supplier wishing to win a competitive bid may be forced into a situation where it disregards quality and efficacy for price.

Historically, ethical providers have strived to differentiate themselves by their level of quality and service. If an under-defined HCPCS code, which includes a wide variety of technologies, is bid then such a provider will either have to reduce its standards or lose business. By more finely dividing the items selected for bidding, and increasing the HCPCS codes, CMS may achieve the benefit of competitive bidding without jeopardizing access where medically appropriate to higher cost, higher technology items.

Exclusion of Surgical Dressings Entirely From the Competitive Acquisition Program (CAP)

The Coalition of Wound Care Manufacturers concurs with CMS in the Agency's exclusion of surgical dressings in the competitive acquisition program (CAP). It is our understanding that surgical dressings are not included for several reasons. First, the plain meaning of section 302(b) supports exclusion of surgical dressings from the CAP. The statute does not reference the section of the Social Security Act pertaining to the surgical dressing benefit [section 1861(s)(5)], nor did it reference surgical dressings by name.

Had Congress intended to include surgical dressings within the items covered under the CAP, it would have done so with clear and unambiguous language referencing these items by name, and/or by referencing section 1861(s)(5) of the SSA. Interpretation according to the plain meaning of section 302(b) fails to demonstrate any intent by Congress to include surgical dressings in the CAP.

Moreover, none of the three categories of items covered by the CAP (which are covered under a separate statutory section 1861(s)(6) of the SSA).- DME and medical supplies, other equipment and supplies, and off-the-shelf orthotics -- include surgical dressings.

Exclusion of Enteral Nutrition From the First Phase of the CAP

The Coalition of Enteral Nutrition Manufacturers agree with two other associations (National Alliance for Infusion Therapy [NAIT] and the National Association for the Support of Long Term Care) that we do not believe enteral nutrition's inclusion in the *first* phase of the competitive bidding program in 2007 would make significant progress towards the two goals of competitive bidding: (1) improve the level of care for Medicare beneficiaries requiring Part B items and services, and (2) reduce Medicare expenditures,

including the amount of beneficiary co-payments. Instead, it would present costly and complicated administrative challenges for CMS and its contractors. As explained below, enteral nutrition presents some of the most challenging obstacles for inclusion in the competitive bidding program, and we believe it would be an difficult selection for the competitive bidding program to begin with in light of CMS' objective of getting off to a successful start of this enormously complex program.

It is clear that CMS has the discretion under the MMA to (a) exclude products and product categories from the 2007 phase of the competitive bidding program, which CMS acknowledges in the preamble to the proposed rule, and equally importantly, (b) exclude products and product categories in particular settings, such as nursing homes, from the 2007 phase of the competitive bidding program.

Section 302 of the MMA expressly distinguishes between where Congress intended the Secretary to exercise significant discretion and those where it did not. The statute provides that the Secretary "shall establish and implement programs under which competitive acquisition areas are established" and that the programs "shall" be phased in so that competition occurs in a certain number of the largest MSAs by certain times. However, the statute also provides that the program "may" be phased in first among the highest cost and highest volume items and services or those with the greatest savings potential, and that the Secretary "may" exempt certain rural and low population density areas and items and services for which competitive acquisition is not likely to achieve significant savings. The statutory language specifically directs the Secretary to establish competitive acquisition areas on a certain schedule, but permits flexibility in design and implementation to encourage efficient operation. By stipulating that the competitive acquisition areas "may differ for different items and services," Congress gave the Secretary wide discretion to choose those products and services that are most amenable to competitive bidding (and to exclude products and product categories that are not) and to first implement the program in the metropolitan statistical areas of his choosing.

These grants of discretion gave the Secretary sufficient flexibility to implement the program in the most effective way possible. It also is clear, then, that if there is evidence that it would be in the interests of a successful competitive bidding program to exclude nursing homes from the first implementation phase, the Secretary has the discretion to do so.

Factors Determining Product Selection

CMS lists these factors as some which determine the products to be selected in competitive bidding in the 2007 phase:

- Level of Medicare expenditures
- Rate of growth in expenditures
- Demonstration project experience

I will address each of the these factors' application to enteral nutrition.

I. <u>Level of Medicare Expenditures</u>

Enteral nutrition is listed in the proposed rule as fourth in total Medicare expenditures for Part B items for 2003. That number, however, is seriously misleading, since enteral nutrition is not a monolithic therapy provided in one setting. Rather, enteral nutrition, for policy purposes, should be divided into three parts:

- (1) Enteral nutrition provided to residents in long term care facilities;
- (2) Enteral nutrition provided in the home to patients who also qualify for the home health benefit; and
- (3) Enteral nutrition provided in the home to patients who do not qualify for the home health benefit.

Historically, a clear majority of Medicare Part B enteral patients are residents of long term care facilities. The percentage of enteral patients who are in long term care facilities increased from 2003 to 2004 to approximately 56%, based on BESS data. This fact is extremely relevant to CMS' ultimate decision of whether to include enteral nutrition in the 2007 phase of competitive bidding. We understand, based on our involvement with CMS in the development of the new Part B quality standards, that the new standards apparently will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients. Enteral patients in long term care facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards.

Similarly, those enteral patients qualifying for the home health benefit are and will continue to be treated pursuant to the home health conditions of participation, not the Part B standards. Thus, the only segment of the enteral patient population who will be subject to the Part B quality standards are the home care patients who do not quality for the home health benefit, a distinct minority of the Medicare enteral patient population. That small segment of the population does not involve Medicare expenditures anywhere near the top ten items of Part B expenditures.

II. Rate of Growth

In its comments, NAIT analyzed enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition do not have any dramatic increases; if fact, the opposite is true. The rate of growth of Medicare allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were \$20,624,897 less than they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

III. Demonstration Project Experience

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS' Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. Importantly, enteral nutrition was removed from that demonstration after the first phase of the project. We believe it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not well suited for competitive acquisition. Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

Importantly, enteral nutrition was the only therapy in the demonstrations where the majority of patients are in a setting other than the home. Competitive bidding clearly was designed by Congress with the home care patient in mind, a concept that the long term care component of enteral nutrition would greatly complicate. We address this issue in greater detail in the section below about long term care facilities.

The reasons for excluding enteral nutrition from the first phase of the competitive bidding program are not limited to the criteria set out above. There are important other bases for omitting enteral from the 2007 portion of competitive bidding, including the following:

Enteral Patients in Long Term Care Facilities

As indicated above, most enteral nutrition is provided in nursing facilities, which presents issues that go far beyond the scope of the competitive acquisition program. It is apparent that CMS and its contractors will be burdened with numerous complex issues to implement the competitive acquisition program even in the most basic manner possible. Attempting to use competitive acquisition for products used in long term care facilities raise a whole host of issues involving access and choice that are not easily resolvable, especially in the immediate timeframe.

Nursing facilities have a special relationship with their residents. In most instances, the facility is the resident's home. The nursing facilities are responsible for coordinating the work of an array of clinicians, providers and suppliers to meet patient health care needs, and they are held accountable for the quality of these services. Nursing homes must meet detailed conditions of participation to participate in the Medicare and Medicaid programs

as well as a wide array of additional quality standards. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism.

For these reasons, most nursing facilities will be extremely concerned if they are forced to admit unfamiliar suppliers into their facilities to provide services, supplies, and equipment to their residents. Nursing facilities must be able to select the suppliers the facilities believe can best enable them to meet resident needs and comply with applicable standards. The competitive acquisition program would interfere with their ability to make these decisions, and potentially interrupt ongoing relationships that have worked to the benefit of their residents.

CMS' demonstration projects did not test a model of competitive acquisition that involved long-term care facilities. This is extremely important, because the proposed rule reflects an overly simplistic view of how long term care facilities operate and how they could fit into the competitive bidding program. We are concerned that the proposed rule appears to reflect a view that a nursing home is simply a supplier that does not have to travel to treat its patients. The only recognition that a nursing home is different in any respect is the provision that a nursing home can limit its participation in the competitive bidding program to treating its own residents. What is surprising is the clear implication that a nursing home actually has to be a winning bidder just to treat its own residents. Residents in nursing homes usually are more impaired than home care patients and require a different regimen of care. Primarily for that reason, it would not be a fair or accurate process to combine nursing home bids with home care bids for a particular products category.

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and definitely should not be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

The Coalition of Enteral Nutrition Manufacturers do not understand how there can be fair and responsible competitive bidding when there are at play different quality standards, different settings of care, and different patient needs. As explained below in the section on competitive pricing principles, competitive bidding requires bidders to have to meet the same requirements in the same context. The nursing home component flies in the face of this principle. With all respect, we do not believe CMS has considered the differences and particular problems the nursing home setting brings to the competitive bidding program. We urge CMS to refrain from selecting products for inclusion in competitive bidding if, as with enteral nutrition, most of the Medicare market for those products is in the long term care setting.

Application of Quality Standards

The competitive bidding program is predicated in large part on the application of the Part B quality standards and the requirement that every participating supplier be accredited in accordance with the accreditation provisions of the proposed rule. This is an important component of the overall scheme of the competitive bidding program, wherein bidders will have similar costs and will benefit from a generally level playing field. That makes perfect sense – again, except with regard to enteral nutrition.

For the enteral patient population, there will not be one set of quality standards – there will be **three** sets of standards: the conditions of participation for long term care facilities; the conditions of participation for home health agencies; and the quality standards under development in connection with the competitive bidding program. This creates a unique problem for enteral nutrition.

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. The proposed rule would require these enteral nutrition suppliers to be accredited for compliance with the Part B standards, even though those standards do not apply to the patients they serve. The absurdity of that result is evident.

Likewise, the provision of enteral nutrition to patients who qualify for the home health benefit would not be subject to the new Part B standards.

It would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the settings of care differ. Further, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

Enteral HCPCS Codes

The enteral formulas within particular billing codes are not interchangeable, which would thwart one an objective of the competitive acquisition program to achieve cost savings by forcing competition not only among Part B suppliers but also among medical manufacturers as well. One of the basic tenets of the competitive acquisition program appears to be an assumption that the program can generate additional savings by limiting coverage to particular products within billing codes that may be cheaper than other products within those codes. For this approach to work, the products within a billing code must be interchangeable. That is not the case for several of the enteral formula billing codes, which were updated within the past few months.

Two codes, B4153 and B4154, are among the two growing codes among the enteral formula codes. As enteral nutrition becomes even more accepted as a viable and cost-effective substitute for parenteral nutrition, we can expect more new enteral formulas for specific diseases and conditions added to these codes. As these codes will contain a growing number of the enteral formulas used in the care for Medicare beneficiaries, this is additional evidence that enteral nutrition is not as suitable for the competitive acquisition program as would be other products that: (1) are clinically interchangeable within their HCPCS codes, (2) do not involve the nursing home resident population, and, (3) do not involve services and other functions that the Medicare program has yet to cover explicitly.

Rebate Program

The Coalitions do not believe that the rebate provision should be included in competitive bidding. Such payments could be considered inducements to beneficiaries and potentially violate the Federal Anti-Kickback Statute. ("Statute") It is fairly certain that rebates provided directly to beneficiaries would fall under the Statute's purview as a form of inducement to beneficiaries in exchange for referrals. The Statute prohibits the knowing and willful offering or giving of remuneration either in return for referrals or with the intent to induce referrals for items and services reimbursed by Medicare.

We appreciate the opportunity to comment on this proposed rule and would happy to discuss any provision with you at your convenience.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Murgart R.PL

Executive Director

Coalition of Enteral Nutrition Manufacturers

Coalition of Respiratory Care Manufacturers

Coalition of Wheelchair Seating Manufacturers

Coalition of Wound Care Manufacturers

Regulatory Affairs PO Box 43 Mail Route 10105 Minneapolis, Minnesota 55440-0043



June 28, 2006

Mark B. McClellan, MD., PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, Maryland 21244-1850

RE: Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule Published in the Federal register on Monday, May 1, 2006.

Dear Dr. McClellan:

I appreciate the opportunity to comment on the proposed competitive acquisition structure on behalf of Allina Hospitals & Clinics (Allina). Allina is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. Allina businesses cover the continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, home (or durable) medical equipment and oxygen, pharmacy, home care and hospice services. Allina serves communities throughout Minnesota and western Wisconsin.

I am writing today specific to the needs of Allina Home Oxygen and Medical Equipment (HOME) and the patients we serve through this important part of our business. Allina HOME has provided oxygen, medical equipment and supplies in our community for over 20 years. We are a full service provider carrying a wide array of medical equipment. We serve patients from pediatrics to geriatrics with varying needs, providing oxygen and respiratory equipment, rehabilitation and mobility equipment, specialty beds as well as other medical equipment and supplies. We serve approximately 55,000 patients annually.

Please review our comments below.

General Comments

The lack of finalized quality standards, no identified accrediting body/bodies, identified bidding areas or identified supplies to bid, and the need for updated data on the population and volume statistics in order to determine what metropolitan sites are include in the Phase I, make it extremely difficult for us to begin to plan for the changes that may result from finalization of any of the changes of the proposed rule.

Mark B. McClellan, MD., PhD June 28, 2006 Page 2 of 5

We understand the requirements for change that come from the MMA and the Deficit Reduction Act, however, we are quite concerned about the significant payment reductions our industry continues to have to swallow. We have already been significantly impacted due to rate reductions to the FEHBP levels and the MMA rate freezes. Further reductions that CMS hopes to gain through competitive acquisition on top of the current reductions and freezes will force a number of suppliers out of business. CMS is already experiencing the positive impacts of the reductions to date.

We are concerned that the additional administrative expense that will be incurred through the implementation of the competitive bidding model may not lead to the real savings that CMS is seeking. We ask that CMS seriously consider the implications this may have on access to supplies and services for beneficiaries in great need.

Access to Services

In Minnesota, 607,125 people are eligible for Medicare. Currently, these individuals receive products, supplies and services from over 450 durable medical equipment (DME) companies. Today, that is one DME provider for every 1350 potential beneficiaries. For the years 2010, 2020 and 2030, respectively, it is projected there will be approximately 671,787; 910,080 and 1,173,339 Medicare-eligible citizens residing in Minnesota. Using existing DME provider statistics, this would mean one provider for every 2,608 potential beneficiaries. We expect that a large number of the smaller providers in rural Minnesota and western Wisconsin may not pursue competitive bidding or not be selected as a CMS supplier and may go out of business without a Medicare contract. CMS must consider the significance of reduced providers on the long-term growth in the Medicare population and their access to services in the rural areas. We are greatly concerned that access to services may be jeopardized in rural Minnesota and western Wisconsin as a result of the competitive bidding model proposed. Under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

Implementation Contractor

We support the development of a separate structure and designation of the Competitive Bidding Implementation Contractor. The complexity of this process and the phasing in of implementation requires a contractor that is focused solely on this work and committed to maintaining the highest level of integrity.

Payment Basis

MSA Selection

CMS has made the decision to exclude New York City, Chicago and Los Angeles from Phase I implementation. We would suggest that at least one of these large metro areas be included in the first phase to allow for rigorous testing of all systems and processes and to show the financial savings that CMS projects to gain from the competitive bidding process.

CMS has provided a list of potential MSA's to be included in Phase I but indicates that these could change with updated census and volumes data. It is challenging to know how to respond to this rule without knowing for sure whether the Minneapolis/St. Paul MSA would be included with updated data.

Mark B. McClellan, MD., PhD June 28, 2006 Page 3 of 5

Allina supports the proposed methodology of combined population and charge data as the basis for MSA selection. In order to achieve the savings that CMS seeks, it is imperative to include charge data an essential component in the MSA selection criteria. We recommend that CMS stagger the bidding in MSA's in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread.

Submission of Bids Under the Competitive Bidding Program

Conditions for Awarding Contracts

We are deeply concerned that the quality standards and the process for accreditation have not been finalized. CMS must allow additional time for providers to analyze the quality standards in conjunction with the proposed rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process. If only accredited providers should be eligible to submit bids, CMS should not proceed with competitive bidding until it is certain that the accreditation work can be accomplished on a timely basis. CMS must identify the criteria it will use to select the accrediting bodies as soon as possible and should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

With only 20-40% of DMEPOS companies currently accredited, we are very concerned about the selected accrediting body's ability to do what needs to be done to assure that all bidding companies are eligible to bid. We are not clear how the grace period will be viewed when it comes to making decisions on awarding the contracts. Will it be viewed as a weakness of the bid if up against other suppliers who are already certified? This should not be the case. In order to have a fair and equitable process, the accrediting body selected must have the resources to meet the volume demands for accreditation prior to the submission of initial bids.

How can CMS legitimately establish whether a supplier actually has the capacity to meet the demand in a CBA? We are concerned about the potentially subjective nature of this assessment. If CMS is only looking at a two-year history of claims data, how does CMS know the ability of the supplier to grow their business? A supplier with a firm financial foundation alone does not necessarily have the other resources required to meet the demand in terms of equipment, service, and customer relationships. We ask that CMS develop specific objective criteria upon which to base this decision. Simply "evaluating capacity to meet demand" is not enough.

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Bidding Requirements

We have issues with the single payment amount determination for capped rental. The implications of reducing the percent down to 7.5% for months 4-13 does not account for the suppliers need to finance the equipment for that period. We ask that you consider maintaining the 10% for the full 13 months or pay an additional fee to the supplier to account for the time value of money related to financing.

Mark B. McClellan, MD., PhD June 28, 2006 Page 4 of 5

We feel very strongly that the service of equipment after the sale is vital to the beneficiary. We support requiring the supplier to maintain and service the equipment after the sale. We ask that CMS develop a clear mandate for suppliers to provide follow up service on all equipment sales and provide appropriate reimbursement for any services provided. We want to be sure that beneficiaries are not left with equipment they have no idea how to maintain and where to go if service is required. We do not want suppliers that may sell equipment without providing the ongoing service required after the sale to end up being selected as a competitive bidder.

CMS proposes to separate out bids for oxygen and oxygen equipment. We strongly urge CMS to keep these products combined under the same contractor. Separating the service and supplies will create confusion for the beneficiaries. They will struggle with which supplier to call for equipment problems versus oxygen supply. There will also be issues related to equipment problems that result from oxygen fills. Oxygen and oxygen equipment and supplies are best provided through the same supplier. This will assure that the equipment is handled appropriately and the beneficiary only needs to deal with one supplier coming to their home and managing their oxygen needs.

Bid Amounts

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item; otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either rational or sustainable.

Rebate Programs

We do not support a rebate program being part of the competitive bidding model. From a compliance perspective, we have significant concerns about the potential for kickbacks and inducements. In addition, rebates will create significant administrative complexity, particularly when the rebate amount may end up exceeding the Medicare co-payment amount. The opportunity to offer rebates also sets up the potential for low bidding versus competitive bidding. If CMS finds it necessary to offer a rebate program, we would suggest that the rebates are not voluntary. If the bids put a supplier in a position to offer a rebate they should be required to do so in order to assure that they are not bidding low just to be selected and then have their reimbursements raised to the median level automatically. This would stop those who would set up deliberate low-ball bidding.

Change in Ownership

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent upon the need to preserve capacity within the MSA.

Suspension or Termination of a Contract

We would like to see greater clarification on the provision for termination of a contract for "convenience." At a minimum, there should be an explicit notice period required prior to termination.

Administrative/Judicial Reviews

We recommend that CMS establish some type of expedited review process specific to contract award decisions. In order to support the highest level of integrity in this process, we seek full transparency of factors influencing contract award decisions.

Mark B. McClellan, MD., PhD June 28, 2006 Page 5 of 5

Final Comments

In closing, we ask CMS to recognize the difficulty of responding to proposed changes without having the fundamental components of the competitive bidding process spelled out explicitly in the rule. With no quality standards, no decisions on accrediting bodies, MSA's that could change, the lack of defined competitive bidding areas, and the absence of a defined set of products to be included in the bidding process, we have tremendous concerns about the promulgation of a final rule of which we have no opportunity to challenge and a very short timeline to implement.

CMS has major work to do prior to this rule going forward and we have much trepidation about the ability of CMS to establish the solid foundation that is essential to support this massive change.

On behalf of our Home Oxygen and Medical Equipment business, Allina Hospital & Clinics sincerely appreciates the opportunity to provide feedback on these proposed changes. We ask that CMS seriously reconsider the aggressive timelines and delay implementation until we can be assured that the fundamental components of a reliable and sustainable competitive bidding process are in place. Please feel free to contact me if you have questions. I can be reached at 612-262-4912.

Sincerely,

Nancy G. Payne, R.N., M.A Director Regulatory Affairs



LifeScan, Inc. 1000 Gibraltar Drive, Milpitas, CA 95035-6312 Tel: 408-956-4900 Fax: 408-956-4966 www.LifeScan.com

(22:4)

Eric P. Milledge Company Group Chairman

June 28, 2006

The Honorable Mark McClellan, MD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention CMS-1270-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Comments on Proposed Rule for Medicare Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues – CMS-1270-P

Dear Dr. McClellan:

On behalf of LifeScan Inc., a Johnson & Johnson company, I am writing in response to the Centers for Medicare & Medicaid Services (CMS) Proposed Rule published in the May 1, 2006 Federal Register for Medicare Competitive Acquisition for Certain DMEPOS and Other Issues. We appreciate the opportunity to submit comments in the spirit of assisting in the successful implementation of a very complex program mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). LifeScan is a leading manufacturer of blood glucose monitoring products and other diabetes management systems. LifeScan is committed to improving the lives of all patients with diabetes today and with continued innovation in the future.

LifeScan commends CMS as it faces the challenge of requiring DMEPOS suppliers to meet consistent, strong quality standards, achieve cost savings in the DMEPOS benefit category, and at the same time, make sure that Medicare beneficiaries get the care and treatment necessary to meet their medical needs. This is an overwhelmingly complex process to implement based on the outcomes of two relatively small demonstration projects that focused on a limited range of products. We urge CMS to be thorough, careful, and conservative in the implementation of Medicare Competitive Bidding for the least disruption for the beneficiaries and to consider program savings for the long term with full consideration of the administrative costs and costs possibly shifted into other benefit areas such as Part A.

Before turning to our comments on specific sections of the proposed rule, we would like to make a few key points that need to be kept in mind when considering DMEPOS used by Medicare beneficiaries to help manage their diabetes.

<u>Diabetes is a life-threatening condition that is affecting a growing number of Americans.</u> A four-part series published in the January 9-12, 2006 issues of the *New York Times* recently catalogued the growing problem of diabetes in the United States, labeling it a "crisis" and calling attention to its "awful toll." A subsequent editorial concluded that this is "the time to develop a

coordinated plan with a long view to take control of diabetes." As of 2005, the Centers for Disease Control and Prevention reported 20.8 million Americans with diabetes, of which over 6 million remain undiagnosed. According to a report released on March 1, 2005 by the Agency for Healthcare Research and Quality (AHRQ), the agency found that "Medicare could save \$1.3 billion annually, and Medicaid \$386 million a year by reducing hospital admissions for diabetes complications. Up to \$2.5 billion—roughly two thirds of the total—might have been averted with appropriate primary care for individuals with complications." The proposed rule listed Medicare allowed charges for diabetes supplies and equipment in 2003 at about \$1.1 billion. However, CMS has also acknowledged that the care of beneficiaries with diabetes consumes roughly 32 percent of total Medicare expenditures. In 2003, Medicare Part A and B benefit payments totaled \$275.9 billion dollars. Thus, in that year, Medicare allowed charges for diabetes supplies and equipment represented only about 1.2 percent of all Medicare expenditures for the care of patients with diabetes, that is \$1.1 billion + \$88.3 billion (\$275.9 billion × 0.32).

Devastating and costly diabetes complications due to lack of appropriate glucose control may include: kidney failure, heart attack, stroke, diabetic retinopathy and other vision problems, neuropathy, and amputation. Regimented self-testing is a critical component to tight glucose management. While it is difficult for any patient to effectively manage a chronic condition, even more challenges exist when older Americans are faced with the daily struggles of proper glucose control often managed by multiple therapies (oral agents, insulin, behavior modification including diet and exercise) and possibly the added burden of treating co-morbidities. If Medicare beneficiary access or continued access to the most appropriate glucose-monitoring device is disrupted, patient compliance with their treatment regimen may be jeopardized and health outcomes could be adversely impacted.

Blood glucose meters and their supplies are an integrated system. Patients must use the unique blood glucose test strips made for their brand of blood glucose monitor, not just any brand of test strips. Blood glucose monitoring is an integrated technology where the test strips are designed specifically and uniquely to work with a specific meter. A glucose meter without the right test strips is worthless. Any required change in manufacturer of glucose meter or test strips would require the beneficiary to change to a different monitoring system. A change in system will require re-education of the patient, which has associated costs.

There are significant differences between blood glucose systems and many other **DMEPOS products**, including the following:

- Patients with diabetes typically go to a supplier, such as a local pharmacy, to obtain their blood glucose monitoring equipment and related supplies; unlike other DMEPOS products, such as oxygen and oxygen equipment, that supplier does not usually deliver the products to the patient's home.
- Patients purchase their diabetes supplies on a regular basis, often monthly; this is a fundamental difference from the typical one-time acquisition of other DMEPOS products, such as a hospital bed or wheelchair.
- Patients now can and do routinely obtain their diabetes supplies from a wide range of sources, including pharmacies, food and drug stores, mass merchandisers, small DME shops, and even mail order companies; they are not restricted to just a few options. In fact, there are more than 56,000 retail outlets now offering diabetes equipment and supplies. Close-to-home access helps minimize the risk that patients will fail to test their blood as indicated if their procurement of diabetes supplies is disrupted or confusing. Also, regular contact with a pharmacist, often an important member of the diabetes management team, can reinforce proper diabetes care. Neglecting to test and manage blood glucose levels can lead to the many costly and devastating issues mentioned previously.
- Variation and fluctuation in patient condition may require product, testing frequency and other adjustments in blood glucose monitoring in order to continue to meet the current needs of the individual. Manufacturers of blood glucose monitoring systems continue to provide innovative products designed to better meet the needs of patients with diabetes.

Unimpeded access to the most appropriate products, including the latest innovations, is very important to a successful diabetes treatment program.

We believe that CMS should approach the topic of diabetes equipment and supplies very carefully, thoughtfully and perhaps incrementally. If these products are subjected to competitive bidding, we recommend that CMS consider these products under its proposal to "phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding". In fact, since diabetes equipment and supplies were not included in the two Medicare competitive bidding demonstration projects, we recommend that any competitive bidding for diabetes supplies and equipment be limited to no more than one competitive bidding area, at least during the first round of bidding. We note, too, that in selecting suppliers to contract with Medicare, CMS would need to take special care to ensure that beneficiaries throughout a competitive bidding area would continue to have convenient geographical access to the many distribution channels available for diabetes supplies today.

KEY COMMENTS AND RECOMMENDATIONS

With the above background in mind, below is our list of key comments and recommendations on the various elements of the proposed rule.

- We strongly support phasing in "some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding" (as discussed in the proposed rule). If CMS decides to subject diabetes equipment and supplies to competitive bidding, it should begin by doing so in no more than one MSA due to the fact that these products were not included in the demonstration projects.
- CMS must assure a reasonable geographic distribution of contract suppliers for DMEPOS products typically obtained by beneficiaries at a nearby retail outlet rather than delivered to their home.
- CMS must assure beneficiaries have reasonable access to a sufficient range of products within a HCPCS code to ensure individual requirements are met.
- CMS must recognize that blood glucose meters and test strips are an integrated system; if subjected to competitive bidding, these products must be included in the same product category.
- We strongly oppose basing the single payment amount on the median of winning bids. No contract supplier should be paid less than their bid amount.
- We strongly oppose <u>requiring</u> beneficiaries to use mail order for replacement supplies and also question a separate national or regional mail order program.
- CMS must adopt special policies in order to allow a manufacturer to serve as a contract supplier.
- CMS policies should require suppliers to inform the relevant DMEPOS manufacturer of any problem with the equipment or supplies so that the manufacturer can make the FDA-required reports and take any other appropriate action.
- CMS must assure that the physician authorization process is as simple as possible, especially during the first few rounds of competitive bidding.

SPECIFIC COMMENTS & RECOMMENDATIONS TO THE PROPOSED RULE

Following is our detailed comments and recommendations to the proposed rule labeled with the captions recommended by CMS.

Payment Basis (proposed §414.408)

CMS is proposing to update the single payment amount set under the competitive bidding process in subsequent years of the contract cycle by the percentage increase in the CPI-U for the 12 month period ending with June of the preceding calendar year. We strongly support this approach. We believe that it will help facilitate the bidding process and provide a reasonable and efficient means for adjusting Medicare payment amounts during each contract cycle.

The proposed rule describes a potential grandfathering process for certain rental agreements. However, we believe that other important transition policies would be needed if certain diabetes supplies and equipment are subjected to competitive bidding in one or more areas. A large number of Medicare beneficiaries are already using glucose monitoring systems (that is, blood glucose meters and compatible test strips), and they may well have been using these items for a long period of time. Unfortunately, it seems quite possible that competitive bidding could force some, many or even most beneficiaries in an area to switch to a glucose monitoring system other than the one they are currently using. This would occur, for example, if contract suppliers offered only one brand of glucose monitoring system—or even several brands—not now commonly used by Medicare beneficiaries. Remember, too, that a beneficiary must have access to both a particular meter and the test strips designed for that specific meter; being allowed access to one without the other would be meaningless.

A sudden forced switching of glucose monitoring systems by large numbers of Medicare beneficiaries in an MSA could have a very disruptive effect not only on beneficiaries, but also on the physicians and diabetes educators who care for them. It could reduce beneficiary compliance with the testing regimen recommended by their physician and lead to a wide range of adverse outcomes. Such forced switching could also have cost implications for the Medicare program if it resulted in substantial numbers of claims for new glucose monitoring systems, a problem that could repeat itself in subsequent rounds of competitive bidding in a given area. Note, for example, that Medicare now generally covers a new glucose meter only once every 5 years, but could find itself paying for new meters every three years under competitive bidding (the presumed length of supplier contracts), if contract suppliers elected to offer different brands of glucose monitoring systems during different contract cycles.

Later in these comments, we offer several suggestions for minimizing the risk of such forced switching. However, even if all our suggestions were accepted, it might still not guarantee that some beneficiaries would not be forced to switch at some point. We, therefore, urge CMS to adopt a transition policy under which beneficiaries now using a specific brand of DMEPOS could continue to have access to the supplies that are compatible with that specific brand for a period of six months following the start of a DMEPOS competitive bidding program in an area. In the case of diabetic equipment and supplies, this would mean allowing beneficiary access to the test strips that are compatible with their current brand of glucose meter. Among other things, this transition policy would provide time for beneficiaries to consult with their physician or diabetes educator to assess the appropriateness of switching to another brand of glucose meter or the need for executing a physician authorization providing for more permanent access to a specific brand of DMEPOS. This transition policy could be implemented in a variety of ways. One option would be simply to require contract suppliers to comply with such a transition policy. In other words, they would agree to provide glucose test strips for the brands of meters now used by Medicare beneficiaries (and even a replacement meter, if necessary), even if such suppliers did not plan to offer that brand of test strips (and compatible meter) on a longerterm basis. Another option would be to give beneficiaries a six-month "grace period" during which they could continue to obtain replacement items from any qualified supplier.

In fact, given the potential disruptive effect if competitive bidding is implemented on a date certain in a large metropolitan area, we would encourage CMS to provide a "grace or transition period" of at least 90 days during which beneficiaries could obtain DMEPOS subject to competitive bidding from non-contract suppliers with these suppliers paid under the applicable fee schedule (or perhaps the single payment amount). When beneficiaries obtain DMEPOS in this way, they could be given educational materials explaining the new program, listing the contract suppliers available in their area and other important information. Expecting a sudden transformation in the DMEPOS marketplace to go smoothly is simply unrealistic, and recent experience with Medicare Part D shows us how difficult it is for beneficiaries to adjust to a new program without some kind of transition. We see nothing in the MMA that would preclude CMS from providing such a "grace or transition period."

The proposed rule also addresses various beneficiary travel scenarios. However, we believe it is unrealistic for CMS to expect a beneficiary traveling into a competitive bidding area to be able to know which DMEPOS items are subject to competitive bidding in that area, identify and locate contract suppliers for that item, and determine which contract suppliers in the area might be offering the specific brand used by the beneficiary (since contract suppliers may well offer different brands). For example, a beneficiary might require replacement test strips that are compatible with their specific brand of glucose meter (which could even be a meter obtained from a contract supplier in the area where the beneficiary maintains a permanent residence). Perhaps they forgot to pack their test strips, or the test strips they brought were misplaced or damaged during the trip. How could CMS possibly assure that such a beneficiary would not have significant difficulties in obtaining the replacement items they need? We do not believe that it could. We, therefore, conclude that CMS should allow beneficiaries who travel to obtain replacement supplies from any supplier, not just contract suppliers in a competitive bidding area.

In the proposed rule, CMS also announces its intent to use its statutory authority to adjust DMEPOS payments in areas not subject to competitive bidding based on its experience under competitive bidding. CMS notes that it has "not yet developed a detailed methodology" for using this authority, and invites comments on this issue. To begin with, we strongly believe that <u>before</u> deciding whether and how it will apply the competitive bidding experience to DMEPOS payments in other areas of the country, CMS should fully assess the impact of competitive bidding on beneficiary access and quality within the designated MSA. Then, once CMS is in a position to develop a detailed methodology for applying the special authority, the agency should publish its proposed methodology for public comment as part of a future rule-making exercise. Since the authority in question is not effective until January 1, 2009 at the earliest, there is plenty of time for CMS to do this. This is an extremely important issue with potentially far-reaching consequences for all stakeholders, including beneficiaries, suppliers, and DMEPOS manufacturers, and it would not be appropriate to implement this special authority merely through manual instructions, especially since the policy in question is likely to easily satisfy the definition of a major rule.

Competitive Bidding Areas (proposed §414.410)

We strongly disagree with CMS' proposal to adopt competitive bidding areas in 2007 and 2009 that go beyond MSA boundaries. We do not believe this would be compatible with the plain meaning of in an MSA. On the other hand, we do agree with CMS' view that it could adopt competitive bidding areas smaller than an MSA. In fact, we would encourage the agency to take advantage of this option to minimize the risk of adverse outcomes from DMEPOS competitive bidding, especially for products not included in the two Medicare demonstration projects, by limiting the area subject to competitive bidding. This approach might also provide a way for minimizing the complications when a selected MSA crosses state (or even DMERC) lines by restricting competitive bidding to the portion of the MSA that lies within a single state or the service area of a single DMERC. It would also have the added advantage of facilitating implementation of the new program, especially in 2007. Moreover, we believe that it would help increase the likelihood of a successful roll-out of the new competitive bidding program.

In terms of the proposed mail order competitive bidding program, we strongly oppose the idea of requiring beneficiaries to use mail order for replacement supplies. We believe this would be anticompetitive, effectively precluding other suppliers, such as retailers and independent pharmacies, from continuing to provide these products to Medicare beneficiaries, and would, therefore, have very serious business implications for the affected suppliers. We note, too, that during the May 22-23, 2006, meeting of the Program Advisory and Oversight Committee (PAOC), CMS staff did not mention that this was one of the options under consideration, and instead emphasized that the agency was not planning to require beneficiaries to use mail order. In addition, we do not see how beneficiaries could be required to use mail order for replacement supplies unless the contract mail order suppliers were at the same time required to offer all brands of such replacement supplies that beneficiaries around the country might need.

Otherwise, a beneficiary might obtain a glucose meter from a supplier, even a contract supplier in one of the many competitive bidding areas scattered across the country, and then be unable to obtain compatible replacement test strips from the contract mail order supplier. Finally, while some beneficiaries may consider mail order the best option for them, other beneficiaries may do better with the kind of support that can only be provided by a face-to-face encounter with a pharmacist or other supplier. In sum, we urge CMS to preserve beneficiary access to mail-order and all other current distribution outlets, instead of forcing all beneficiaries to use only mail order (or any other single type of distribution outlet) for certain products or under certain circumstances.

Beginning in 2010, CMS is proposing to phase in a national or regional mail order competitive bidding program for certain items. We urge CMS to proceed cautiously in this regard. Since CMS will also have implemented competitive bidding in 80 MSAs by that point with more MSAs expected to be added after 2009, we believe there is a serious risk of confusion if a regional or national mail order competitive bidding program is overlaid on top of the regular competitive bidding program. In addition, since mail order firms will be permitted to bid during the early rounds of the competitive bidding program, it is not clear how a separate mail order program be made compatible with what has already occurred. For example, some mail order firms may have been selected as contract suppliers during the early rounds of the competitive bidding program. while other mail order firms were not selected or chose not to bid. Mail order firms selected during Rounds 1 and 2 for specific MSAs could end up being supplanted by other mail order firms choosing to bid on a regional or national basis. To the extent that CMS is planning to extend the competitive bidding program beyond the 100 MSAs already envisioned, the agency should simply continue to allow mail order firms to compete on the same basis as other suppliers. In short, we question the whole notion of a separate competitive bidding program for mail order firms as opposed to a program under which mail order firms are allowed to compete fairly against other suppliers.

Criteria for Item Selection

The proposed rule notes that CMS "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." As noted earlier, we strongly support this approach, especially with respect to DMEPOS products and supplies, such as glucose monitoring equipment, not included in the two Medicare demonstration projects. In fact, as we understand it, CMS expressly decided <u>not</u> to include glucose monitoring equipment in the Medicare demonstration projects, and we believe those demonstrations provide relatively limited information about how competitive bidding would work for products typically obtained at a wide range of retail outlets (as opposed to products delivered to the patient's home).

Among other things, the concept of phasing in some product categories would allow CMS to gain experience with different product distribution channels (for example, DMEPOS typically obtained by a beneficiary at a local retail outlet compared to products typically delivered to the patient's home). This approach would also simplify implementation during the early rounds of competitive bidding and minimize the risk of adverse beneficiary outcomes. We cannot emphasize enough how important we believe it is for CMS to avail itself of every possible means for proceeding cautiously as it implements the new competitive bidding program. Phasing in certain product categories will help CMS identify issues and make refinements prior to subjecting a large number of Medicare beneficiaries to a new system. As noted earlier, we recommend that any competitive bidding for diabetes equipment and supplies be restricted to a single competitive bidding area, at least during the first round of the bidding process.

As acknowledged in the proposed rule, the MMA gives CMS the authority to "exempt items for which the application of competitive bidding is not likely to result in significant savings." In terms of diabetes equipment and supplies, we believe that the history of Medicare DME fee schedule changes for these products since 1998 (described in more detail below) raises serious questions about whether competitive acquisition could achieve such "significant savings" because the Medicare program has already implemented a number of cost saving methods in this area.

To begin with, the MMA <u>froze</u> payments for glucose meters, test strips and lancets for 2004. It also mandated payment <u>reductions</u> for test strips and lancets for 2005 of 4.1 percent and up to 5.3 percent, respectively. The MMA also specifies a continuing payment <u>freeze</u> for glucose meters, test strips and lancets for the years 2006, 2007 and 2008. Payments for glucose meters, test strips and lancets were previously frozen in 1998, 1999, and 2000, and again in 2002. In sum, for the period 1998 to 2006, payments for glucose monitors, test strips and lancets were either frozen or reduced in 7 of these 9 years, while from January 1998 to May 2006, the consumer price index for all urban consumers (U.S. urban average) rose by almost 25 percent. This history causes us to question the feasibility of achieving significant additional Medicare savings through competitive acquisition <u>without</u> compromising Medicare beneficiary access or quality.

Submission of Bids Under the Competitive Bidding Program (proposed §414.412) We are concerned that CMS may not allow a sufficient amount of lead time for DMEPOS suppliers to submit bids. We believe that considerable advance notice will be required to permit suppliers in designated competitive bidding areas to negotiate with DMEPOS manufacturers, and fully assess the cost implications of new DMEPOS supplier quality standards and the related accreditation process (including the specific fees that the accrediting bodies yet to be selected by CMS will be charging for their accreditation services). We believe, for example, that it would be unrealistic for CMS to issue requests for bid (RFBs) immediately following publication of the final rule and then give suppliers only a short period of time to develop and submit their bids. Even DMEPOS manufacturers not planning to serve as direct suppliers will need some time to adjust once CMS has actually announced the 10 MSAs selected for Round 1 of competitive bidding and the specific product categories that will be used in each of these MSAs. We, therefore, recommend that RFBs not be issued until 60 to 90 days following publication of the final rule in order to give suppliers and other stakeholders time to review the rule and understand its implications without also having to simultaneously deal with the RFBs. We also urge CMS to give suppliers in designated competitive bidding areas at least 90 days to submit their bids following release of the RFBs for Round 1.

Moreover, ideally, suppliers would not have to submit bids until they have been accredited as meeting the new supplier quality standards and can therefore be certain they have built into their bids all the costs of complying with those standards. As we understand it, during the recent PAOC meeting, a representative of one of the major accrediting organizations in the country said that it would take 3 to 6 months for suppliers in the designated competitive bidding areas to be accredited once CMS has selected the accrediting organization(s). In any case, as we will emphasize again later in our comments on the single payment amount, if supplier bidding ends up preceding supplier accreditation, then CMS must ensure that only the bids of accredited suppliers end up being used in calculating the single payment amounts for DMEPOS items under the competitive bidding program.

The proposed rule does not propose specific product categories but assumes that interested bidders would be required to submit bids on all items included in a product category. However, for some DMEPOS, manufacturers are now serving as direct suppliers. In fact, for some products (for example, insulin pumps), manufacturers may now be the principal source of the product. Medicare supplier and claims data should help CMS assess this. For other DMEPOS products, manufacturers might wish to begin serving as direct suppliers under competitive bidding. However, manufacturers of specialized equipment might obviously not be in a position to bid on every item included in a product category, especially if CMS decides to create very large categories. This creates a problem. CMS could attempt to carefully design product categories to avoid shutting out manufacturers or it could adopt special rules for manufacturers wishing to bid. Of course, the latter would also require adjustments to the methodology for calculating composite bids (or their equivalent) if a manufacturer were not required to bid on every item in a product category. We have no definitive solution to suggest at this time but we do believe it would be a mistake for CMS to exclude manufacturers from competitive bidding—and even seriously

disrupt the existing marketplace for certain products. In this regard, we also wish to note that a bidding manufacturer would obviously only be in a position to offer their own brands of DMEPOS, but we again do not believe that this should automatically exclude them from the opportunity to bid and serve Medicare beneficiaries.

If CMS elects to subject elements of the diabetes supplies and equipment policy group to competitive bidding, we urge the agency to recognize that blood glucose monitors and test strips function as a system (a specific brand of test strip is only compatible with a specific brand or very closely related brands of glucose monitors). This means that both components of the system should either be excluded from competitive bidding in an area or both components included in the same product category. In fact, if CMS decides to implement competitive bidding for blood glucose monitoring equipment, we believe that a reasonable product category would include the basic code for blood glucose monitors (E0607), the code for test strips (A4253), the code for control solutions (A4256), the code for lancets (A4259), and the code for lancing devices (A4258).

Conditions for Awarding Contracts (proposed §414.414)

The proposed rule notes that individual products subject to competitive bidding will be identified by HCPCS codes and "will be further described in the RFB." However, no details are provided to explain what such further description might entail. Such further description of products in the RFBs would provide a means for assuring continued beneficiary access to a range of products now reported by a single HCPCS code. For example, for any single HCPCS code, CMS could specify product features that would need to be included among the brands offered by a contract supplier, or specify a minimum number of different brands that would need to be available to Medicare beneficiaries. In the context of blood glucose meters, this is important because nearly all meters are reported by the same HCPCS code (E0607), although they have different handling properties, different display readabilities (e.g., Spanish displays), and different data managing capabilities (which may, in some cases, provide clinical advantages), and any one of these differences can be extremely important to the individual patient. A "least common denominator" meter is not likely to meet everyone's needs. Failing to recognize differences between products could also have the unintended consequence of stifling innovation aimed at improving this category of products.

As part of its "further description" of products, CMS could also specify the need to offer those that carry adequate warranties (which are typically offered by manufacturers, <u>not</u> suppliers). For some DMEPOS products, it could specify the need to offer products that are backed up by manufacturer-run patient support systems (for example 24-7 toll-free lines that accommodate the principal languages spoken by Medicare beneficiaries living in a competitive bidding area), especially for products where this is the common (but not necessarily universal) practice today.

Companies such as LifeScan provide such patient support systems, but CMS should not assume that all manufacturers of diabetes equipment and supplies do so or will continue to do so. In fact, it seems quite possible that contract suppliers could end up offering DMEPOS products lacking the most advanced features or the current level of patient support in order to bid low (or to maximize their profits after they are selected as contract suppliers). We realize that the supplier quality standards may address some of these concerns. However, we urge CMS to recognize that not all products reported with a single HCPCS code today are equivalent in quality, and so a competitive bidding system that does not further specify the expected quality of deliverables risks creating a two-tiered system, under which Medicare beneficiaries in competitive bidding areas have access to only a small subset of the products available to beneficiaries in areas not subject to competitive bidding, and those products may lack important features as compared to the other products in the marketplace.

To the extent that supplier decisions about product offerings would force beneficiaries to switch from the DMEPOS products they now use to other brands, bidding suppliers should be required

to include a plan for educating patients about the use of the new product so that the potentially negative consequences of a forced switch are minimized.

CMS proposes to have bidding suppliers indicate how many units of each product they would be able to offer in a competitive bidding area. However, it is not clear how CMS plans to verify whether these supply estimates are reasonable. For example, the ability to offer a product must specifically include the ability to support the volume of product offered (for example, patient counseling, training, handling patient calls in a timely fashion, working with prescribing physicians, etc.). CMS also needs to understand that, at least for some DMEPOS products, the supply might not be completely within the control of the bidder. For example, if a supplier's promised capacity and bid price assumes that a store brand or a product that now comprises a tiny share of the marketplace will be the only one offered under one of the HCPCS codes in a product category, how will CMS assess whether the manufacturer of that particular product will be capable of increasing supply fast enough to meet beneficiary needs for that item?

In the proposed rule, CMS promises to match supply and demand in selecting the number of winning suppliers. However, no mention is made anywhere of the need to assure that winning suppliers will be geographically distributed across the entire competitive bidding area, rather than concentrated in one portion of the area. While this may be less of a concern in the case of DMEPOS products typically delivered to a beneficiary's home, it is a major issue when the products are typically obtained by the beneficiary from a retail outlet. Today, beneficiaries most likely obtain such products from a retailer near their home. Although the proposed rule generally requires contract suppliers to serve an entire competitive bidding area, in the case of retail outlets, a beneficiary must first travel to a specific retailer to request service. We acknowledge that it will be very difficult to assure a reasonable geographic distribution of contract suppliers, since this will require an intimate knowledge of the marketplace in each competitive bidding area. However, without great care, the competitive bidding program could end up disadvantaging lower-income beneficiaries living in rural or inner city areas, minorities, or other vulnerable subsets of beneficiaries. And in the case of diabetes equipment and supplies, these might be the very population subsets with high rates of diabetes and most in need of unimpeded access to blood glucose monitoring equipment. In fact, CMS might find it necessary to select suppliers with bids above the pivotal bid (or its equivalent) in order to assure full coverage of an area.

We note Congressional sensitivity to this very issue in Medicare Part D, where prescription drug plans are expected to have a network of pharmacies that ensures "convenient access" and TRICARE standards are used as a model for assessing this. For example, under Medicare Part D, at least 90 percent of Medicare beneficiaries living in urban areas and served by a particular Part D plan, on average, must live within 2 miles of a network pharmacy. We recommend that Medicare's DMEPOS competitive bidding program be designed to assure a similar level of "convenient access," at least for diabetes supplies.

Other negative outcomes are also possible in selecting contract suppliers under the proposed methodology. We believe it would be anti-competitive, for example, for CMS to select a single chain of drug stores (with multiple locations) to serve a competitive bidding area. While this would technically satisfy the requirement to select at least two suppliers for an area, this "two" would in reality represent a single corporate entity. CMS has shown sensitivity to the notion of market concentration by proposing to restrict the size of the marketplace that a supplier network could represent, but this same issue could arise outside of the network context.

Determining Single Payment Amounts for Individual Items (proposed §414.416)

CMS is leaning in favor of setting the single payment amount for a HCPCS code at the median of the bids at or below the pivotal bid for the code. **We strongly oppose this**. To begin with, the proposed methodology does not propose to "weight" the bids by the amount of product being promised by the bidding supplier. Thus, the bid from a supplier proposing to provide 100 units would be treated the same as a bid from a supplier proposing to provide 100,000 units. This

could end up meaning that the single payment amount would be below—perhaps substantially below—the amount bid by the suppliers with the capacity to serve the bulk of the competitive bidding area.

Second, as noted earlier in these comments, CMS must only use the bids of accredited suppliers in calculating the single payment amount, and so if supplier bidding precedes supplier accreditation, then CMS will have to determine whether presumptive "winning" bidders have subsequently been accredited and thereby qualify to have their bid used in the payment calculation. Otherwise, the bid of an unaccredited supplier could inappropriately bias the calculation of the single payment amount (for example, that bid might be unduly low simply because the supplier had not taken into account all the costs involved in meeting quality standards).

Third, as CMS acknowledges, the Medicare DMEPOS competitive bidding demonstration projects did not base payment on the median of winning bids, but an adjustment factor was applied in order to minimize having the payments set below the prices bid by winning suppliers. As a result, CMS does not have experience using the median of winning bids in a competitive bidding program, and it is hard to predict what impact this approach would have. We believe that the same kind of payment adjustment used in the demonstration projects or another equivalent approach should be used to help assure that winning bidders actually win. For example, perhaps CMS could set the single payment amount at the 90th percentile of winning bids or no lower than 5 percent below the highest winning bid. If the median is used as proposed, some winning bidders may be forced to reduce beneficiary access, product quality and beneficiary service in order to live within the single payment amount.

CMS is proposing to allow contract suppliers with bids below the single payment amount to offer rebates to beneficiaries equal to the difference between their actual bid and the single payment amount. We join the members of the PAOC in believing that such rebates could lead to fraudulent and abusive practices by both contract and non-contract suppliers. We urge CMS to reconsider this proposal.

Terms of Contracts (proposed §414.422)

The proposed rule mentions a non-discrimination contract provision, which is intended to assure "that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers." Unfortunately, the proposed rule provides very little detail about what would be expected or how CMS would assure that the provision was being met. It is not clear, for example, whether this contract provision relates to the range of products reported by a single HCPCS code. However, contract suppliers may be inclined to offer fewer choices of product within a particular HCPCS code under the Medicare competitive bidding program than they offer to other customers. The final rule needs to discuss this issue in more detail so that suppliers and beneficiaries will be able to understand what CMS has in mind, and know what protections are being afforded to beneficiaries by the non-discrimination provision.

We note, too, that the draft bidding sheet (Form B) asks bidding suppliers to list the models of DMEPOS products for each HCPCS code, but there appears to be considerable uncertainty, both inside and outside of CMS, about what this information is intended to imply and how it will be used by CMS in evaluating bids. For example, by listing a specific brand, would the bidding supplier be making a commitment to offer that brand throughout the contract period? Will CMS be using the information to determine whether a bidding supplier is planning to offer an adequate range of brands or choices for each HCPCS code? If so, how does CMS propose to do this? Would the model information submitted by bidding suppliers serve as a means for making an "up front" assessment of whether a supplier would be likely to satisfy the proposed non-discrimination contract term? Would a bidder later be able to add new brands (for example, new products on the market) or would Medicare beneficiaries be denied access to products brought to market after bids were submitted or awarded (for the full period of the Medicare supplier contract)? We doubt

this is what CMS intends and urge CMS to explain the purpose of requesting such brand information.

The proposed rule also proposes to place the burden of repairing or replacing patient-owned items subject to competitive bidding on contract suppliers. In doing so, however, we believe that CMS may misunderstand what happens today and the respective roles of suppliers and product manufacturers in the process. For products such as glucose monitors, for example, it is a manufacturer warranty that applies, not a guarantee on the part of the supplier. More importantly, FDA regulations require manufacturers, not suppliers, to evaluate product complaints and inform the agency, as required under the Medical Device Reporting regulations (21 CFR 820.198 and CFR 803), in cases where problems are considered to be "reportable" events. CMS policies on item repair (and/or supplier quality standards) could, therefore, become an obstacle to manufacturer discharge of these regulatory obligations. CMS policies should instead require suppliers to inform the relevant DMEPOS manufacturer of any problem with the equipment or supplies, including any adverse effects involving Medicare beneficiaries, so that the manufacturer will be in a position to address the problem, report to the FDA, or take other corrective action if needed. In addition, CMS policies should in no way imply that a product warranty is the supplier's legal obligation as opposed to that of the product manufacturer.

Opportunity for Participation by Small Suppliers

The MMA requires the Secretary to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS competitive bidding program. In our view, the proposed rule has not gone far enough in this regard. CMS has proposed a definition of "smallness" that includes roughly 90 percent of all suppliers. We doubt that Congress intended to mandate special procedures for nearly all suppliers, as opposed to a smaller subset of suppliers. In addition, while nearly all suppliers may meet the Small Business Administration's definition of a small business, this masks a wide range of "smallness."

We urge CMS to provide a fairer and more balanced commercial climate for small suppliers. One option would be to permit truly small suppliers (perhaps defined by the number of full time equivalent employees in the firm, or by total revenues substantially below the SBA cut-off for a small business) to serve less than the full competitive bidding area. Another option would be to permit truly small suppliers to send in a modified "bid" that simply promises to accept the single payment amount or even to be deemed as having submitted such a bid, rather than requiring them to submit a complete bid. This approach would have the added advantage of preventing the bids of very small suppliers from having an undue (and inappropriate) impact on the calculation of the single payment amount in a competitive bidding area. In addition, special treatment for truly small suppliers is likely to have a positive impact on beneficiary access, since smaller suppliers are more likely to be serving less populated areas of a competitive bidding area and located closer to the homes of beneficiaries living in these less populated areas than other contract suppliers.

Opportunity for Networks (proposed §414.418)

CMS is proposing to allow suppliers to form networks for bidding purposes, and sees this as one of its special accommodations for small suppliers. However, a very similar option offered to suppliers during the Medicare demonstration projects went unclaimed. We anticipate a similar outcome here. The proposed network option appears to be very complicated in design and it seems rather unlikely that a group of interested suppliers would be able to create a network in time to submit bids.

Education and Outreach

The proposed rule provides relatively little information about CMS' plans to educate beneficiaries about the competitive bidding program. We believe that this issue should be discussed in more detail in the final rule. We believe that CMS may underestimate the difficulty of such an education program, given the range of products that might be subjected to competitive bidding, the large number of suppliers now serving Medicare beneficiaries (including

essentially every local pharmacy), the range of items (and brands) covered by many HCPCS codes for DMEPOS and the diversity of features offered by these products. In addition, there are the further complications that arise when beneficiaries travel. According to the proposed rule, traveling beneficiaries will have to determine whether the area they are visiting is a competitive bidding area, which DMEPOS are subject to competitive bidding in that area, where the contract suppliers are located, and which brands each of these contract suppliers has chosen to offer for purposes of the competitive bidding program. In effect, a beneficiary coming from a non-competitive bidding area and using a specific brand of glucose meter could either find it extremely difficult—or even impossible—to locate replacement test strips for that brand if glucose testing equipment were subject to competitive bidding in the area they were visiting.

Moreover, since the beneficiary would be visiting and perhaps far from their usual source of medical care, even a physician authorization might be difficult to execute. We again urge CMS to consider allowing beneficiaries who travel to a competitive bidding area to obtain replacement supplies from any supplier, not just contract suppliers, in that area. This would greatly simplify the beneficiary education process.

Monitoring and Complaint Services for the Competitive Bidding Program

The proposed rule provides no specifics about the proposed complaint monitoring system (for example, how the system will work or where it will be housed). The final rule needs to provide more information about this system. In addition, we urge CMS to assure that ombudsmen are designated for each competitive bidding area and that they play an important role in addressing and resolving beneficiary complaints. The proposed rule appears to suggest that CMS has not yet firmly decided whether to create an ombudsman program for the DMEPOS competitive bidding program. We believe that ombudsmen are absolutely essential to protect Medicare beneficiaries and that experience during the Medicare competitive bidding demonstration projects confirms this.

Physician Authorization/Treating Practitioner (proposed §414.420)

CMS is proposing to implement a physician authorization mechanism under which a physician or treating practitioner would be able to indicate that a specific brand of DMEPOS is necessary to avoid an adverse medical outcome (that is, when a range of products are described by a single HCPCS code and the specific brand in question is not otherwise available from contract suppliers).

We urge CMS to keep the physician authorization process as simple as possible, especially during the early rounds of the competitive bidding program. A "dispense as written" approach or simply documentation in the medical record should suffice. In addition, the issue or definition of adverse outcome will vary from one category of DMEPOS to another and may not be amenable to a "one size fits all" policy. For example, in the case of glucose monitoring equipment, specific features of a glucose meter and/or the test strips compatible with that meter may be essential in facilitating patient compliance with the physician-recommended testing regimen. Thus, different patients may require different products (all currently reported under the same HCPCS code) to meet their needs. A beneficiary forced to switch to another brand of meter or to use a meter with limited functionality might simply choose to test less frequently or not to test at all, which could adversely affect his or her glucose control. In this case, while the adverse outcome might not be immediate, it is well understood that poorly managed diabetes may ultimately lead to adverse outcomes that could have been prevented or ameliorated.

In sum, to the extent that CMS attempts to define the term "adverse outcome," we urge the agency to recognize that the term has different implications for different categories of DMEPOS. For example, since blood glucose monitoring is not a treatment per se, the concept of adverse outcomes in the case of such equipment is far different from that for other DMEPOS used for treatment purposes, such as TENS devices, infusion pumps, and nebulizers. Given all of this, we

believe that Medicare beneficiaries would be better served if CMS did not attempt to "second guess" physicians on the issue of adverse outcome, especially during the early rounds of the competitive bidding program.

We recommend, instead, that CMS monitor the use of physician authorizations, determine the reasons for their use (for example, perhaps because contract suppliers are only offering products with less advanced features that will not adequately meet their patients' needs), and assess the need for potential changes in the competitive bidding program, not solely in the physician authorization process, based on this experience. Ideally, the competitive bidding program will be designed and implemented in a way that minimizes the need for physician authorizations, especially since such authorizations are a very inefficient means for assuring beneficiary access and quality.

In implementing the physician authorization process, CMS also needs to be mindful of the fact that certain DMEPOS products, such as replacement test strips for a particular brand of glucose meter, will be needed on a regular basis. To the extent that a physician determines that a patient should use (or continue to use) a specific brand of glucose meter, CMS should not require a physician authorization each time a beneficiary must obtain replacement test strips for such meter. Instead, if a physician authorization is required for replacement test strips, one such authorization no more frequently than every six months should be all that is required. Otherwise, the physician authorization process would become extremely burdensome for products requiring frequent replacement supplies and thereby impose a significant barrier to beneficiary access. Under not too dissimilar circumstances now, when a particular beneficiary requires, for example, more than 100 glucose test strips per month, the ordering physician must document in the patient's medical record the need for a frequency of testing that exceeds the utilization guidelines, and new documentation must be present at least every six months, not every time the patient requires a new supply of test strips. A similar documentation requirement could be used to implement the physician authorization mechanism under DMEPOS competitive bidding.

Gap-filling (proposed §414.210(g))

LifeScan is extremely concerned about the proposed new functional technology assessment methodology for gap-filling. While CMS notes that this new methodology would involve a functional assessment, a price comparison analysis, and a medical benefit assessment, the proposed rule does not provide much detail about exactly how this would be done, what data would be used, what role product manufacturers and other stakeholders would have in the process, and how the process would be made reasonably transparent. As it stands, we view the proposed functional assessment as a kind of "black box" and this makes it difficult for us to offer thoughtful comments. We urge CMS to eliminate this provision from the final rule and use a separate rule-making process to request comments on a more fully-developed proposal, one that includes specific examples of how this kind of assessment would be done with appropriate input from stakeholders.

Regulatory Impact Analysis

The proposed rule does not provide estimates of the full costs of administering the competitive bidding program. We believe these costs will be quite significant, especially if the program is managed in a way designed to minimize adverse outcomes for beneficiaries, such as those that would arise from access barriers and reductions in quality.

We also urge CMS to take into account the potential impact of the competitive bidding program on other Medicare expenditures. We fear, for example, that savings from competitive bidding could simply translate into increased Medicare expenditures for other services, such as emergency department visits and hospital admissions, especially if competitive bidding ends up reducing beneficiary access to high quality DMEPOS. Although not directly addressing DMEPOS competitive bidding, a report published in the June 1, 2006 issue of the *New England Journal of Medicine* by Hsu et al. indicates how a cost-savings intervention (a cap on annual drug benefits)

can increase Medicare expenditures for services such as emergency department visits and nonelective hospitalizations, and even increase beneficiary deaths.

Fee Schedule Updates for Class III Devices

The background section of the proposed rule requests comments on the appropriate Medicare fee schedule percentage change for Class III durable medical equipment for 2007 and 2008. CMS plans to consider these comments along with recommendations made by the Government Accountability Office (GAO) in a March 2006 report.

We believe that the GAO report has some serious flaws and is misleading. Rather than recommend a specific update factor for Class III devices, the report simply says that future updates should be "the same" or "uniform" for both Class III and Class II devices. In addition, the report compares unfavorably to the standard payment adequacy assessments and payment update recommendations found each year in the March report of the Medicare Payment Advisory Commission (MedPAC). For example, in its March 2006 report, MedPAC assesses the adequacy of Medicare payments for hospital inpatient and outpatient services, physician services, outpatient dialysis services, skilled nursing facility services, home health services, long-term care hospital services and inpatient rehabilitation facility services. Following each detailed assessment, MedPAC then recommends an update policy for each provider category for the coming year. The GAO report never justifies its alternative assessment methodology or its failure to take into account changes over time in manufacturer costs for Class III devices.

In short, we urge CMS not to rely on the GAO report in reaching a decision about the appropriate update factor for Class III devices for 2007. Until a more thorough assessment of the issue can be completed, we recommend that the update for Class III devices continue to be based on changes in CPI-U.

We welcome the opportunity to comment on the proposed rule and we hope these comments will help CMS craft a final rule that will assure continued beneficiary access and quality.

Sincerely,

Eric P. Milledge

Company Group Chairman





June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Mobile, LLC located in Mobile, Alabama. We are a 174-bed facility employing 220 staff. Our services include Physical, Speech and Occupational therapy, which greatly enhance the quality of life of our residents.

The proposed rule is a significant change to the current "any willing provider" environment. As a caregiver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Stephen Davis, Administrator

Crowne Health Care of Mobile, LLC

(228-

June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P ... P.O. Box 8013

Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the administrator at Crowne Health Care of Fort Payne, a 123 bed skilled nursing facility offering Physical Therapy, Occupational Therapy and Speech Therapy services to the residents of Dekalb County, Alabama and the surrounding area.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, I believe that requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS item could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Fort Payne we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

James W. Turnipseed

(228-2)

June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013 Crowne

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Atmore Nursing Center, LLC. This 100 bed skilled nursing facility is located in Atmore, Alabama and employs over 100 people.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

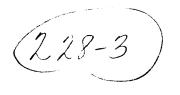
At Atmore Nursing Center, LLC we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Cindy Lee Administrator



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013



To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Parkwood Health Care Facility. We are a 74 bed skilled nursing facility located in Phenix City, Alabama and employ approximately 100 full time and part time employees. Parkwood Health Care offers skilled nursing care and specialized rehabilitation services including Physical Therapy, Occupational Therapy, Speech Therapy and transitional rehab nursing programs.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Parkwood Health Care we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Teri Roop, RNO, NHA

SUMTER HEALTH AND REHABILITATION, L.L.C.

1505 East 4th Avenue York, AL 36925 Phone (205) 392-5281 Fax (205) 392-7285



June 27, 2006

Department Of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD. 21244-8013

To Whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies("DMEPOS").

I am the Administrator at Sumter Health & Rehab, LLC located at 1505 East 4th Ave., York, Alabama 36925. We are a Skilled Nursing Home with 125 licensed beds, 150 employees, and offer Speech Therapy, Physical Therapy, and Occupational Therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Sumter Health & Rehab, LLC we have numerous residents whose care could be interupted as a result of this implementation-jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

SUMTER HEALTH AND REHABILITATION, L.L.C.

1505 East 4th Avenue York, AL 36925 Phone (205) 392-5281 Fax (205) 392-7285

I appreciate your attention to this matter.

Joe E. Dampeer, NHA

Sincerely,

NORTHPORT HEALTH AND REHABILITATION, L.L.C.

600 34th Street Northport, AL 35476 Phone (205) 339-5900 Fax (205) 339-5902



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To Whom It May Concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Northport Health and Rehabilitation, LLC which is a 78 bed facility located in Northport, Alabama. We have approximately 98 employees and offer specialized services including Physical, Occupational and Speech therapy, wound management, IV therapy, etc...

The proposed rule is a significant change to the current "any willing provider" environment. As caregiver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

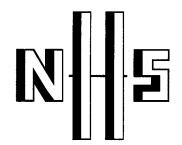
Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Northport Health and Rehabilitation, LLC, we have numerous residents whose care could be interrupted as a result of this implementation - jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

David Estes



COVINGTON COURT HEALTH AND REHAB CENTER

4500 Old Greenwood Road Fort Smith, Arkansas 72903 Phone (479) 646-5700 Fax (479) 646-5956



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Covington Court Health & Rehab. We are located at 4500 Old Greenwood Road, Fort Smith, Ar. We are 115 bed facility with 5 private rooms and 55 semi-private rooms. We our staffed with 110 employees. We are both a short-tem and a long-term care. We have a fully staffed on- site therapy department that provides PT, OT and ST services.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

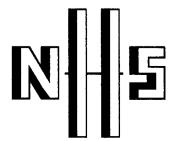
At Covington Court Health & Rehab we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

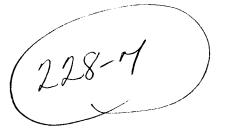
I appreciate your attention to this matter.

Mary B Gilbert

dincerely.



HEALTH SERVICES



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Regional Operations Director with Health Services, located in Cleveland, Tennessee. We operate over 13 Long Term Care facilities with over 1300 beds in nine States, we employ well over 1000 staff members.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Health Services facilities we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

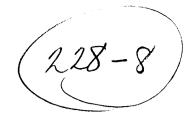
Sincerely,

Blaine Sheffield

Regional Operations Director Health Services

COLUMBIANA HEALTH AND REHABILITATION, L.L.C.

22969 Highway 25 Columbiana, Alabama 35051 Phone (205) 669-1712 Fax (205) 669-6169



June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To Whom It May Concern,

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics, and other supplies ("DMEPOS").

I am the Administrator at Columbiana Health & Rehabilitation, LLC. Our address is: 22969 Hwy 25, Columbiana, AL 35051. The phone number is: (205) 669-1712. Our fax number is: (205) 669-6169. We currently have 63 beds. We have close to 85 employees. Our therapy department offers speech, occupational, and speech therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a caregiver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide what the seniors need and deserve.

At Columbiana Health & Rehabilitation we have numerous residents whose care could be interrupted as a result of this implementation - jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel that it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or

COLUMBIANA HEALTH AND REHABILITATION, L.L.C.

22969 Highway 25 Columbiana, Alabama 35051 Phone (205) 669-1712 Fax (205) 669-6169

compromised by a mandate whose impact, although well intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Carol Knight, NHA Administrator

OPP HEALTH AND REHABILITATION, L.L.C.

P.O. Box 730 115 Paulk Avenue Opp, AL 36467 Phone (334) 493-4558 Fax (334) 493-6112

June 28, 2006

Attention: CMS-1270-P

P. O. Box 8013

Baltimore, MD 21244-8013

Department of Health and Human Services

To Whom It May Concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Opp Health and Rehabilitation, P. O. Box 730, 115 Paulk Avenue, Opp, Al. 36467. We are a 197 bed facility and we employ approximately 200 employees. We have an exceptional rehab team which consist of Physical Therapy, Occupational Therapy, and Speech Therapy. Our therapy team strives at restoring our residents to their original day to day living or as close to that goal as we can get.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

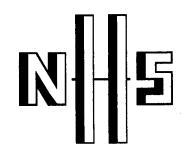
At Opp Health and Rehabilitation, we have numerous residents whose care could be interrupted as a result of the implementation - jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely, Welcu

Yvette Welch Administrator



228-

228-10

SPRINGDALE HEALTH AND REHABILITATION

102 N. Gutensohn Springdale, AR 72762 Phone: (479) 756-0330 Fax: (479) 872-1502

June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Springdale Health & Rehabilitation Center. We are located at 102 North Gutensohn in Springdale, Arkansas 72762. The facility is equipted with 120 beds, and our average number of employees is 105. Our facility is a skilled nursing facility that meets the long-term care and rehabilitation needs of our surrounding communities. We provide a variety of services like intensive rehabilitation, traditional long-term care, and transitional care.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Springdale Health & Rehabilitation we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Deanna Shackelford, Administrator



June 28, 2006

Southern Care, LLC dba Sunset Manor 251 Sunset Place Guin, AL 35563 (228-11)

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Southern Care, LLC, dba Sunset Manor. We are a 71 bed nursing home with 110 total employees in a rural area.

The proposed rule is a significant change to the current "any willing provider" environment. As a caregiver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Sunset Manor we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

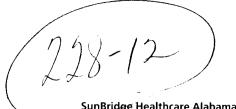
I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

Also, of the many contracts for services and supplies that we are engaged, we always try to get the best possible price. Although a vendor may have a cheaper price, many times their services reflect their cost savings by poor customer service and delivery delays. I'm afraid if we were mandated to select the "lowest bid" we would be forced to select a provider that did not meet our residents' needs.

I appreciate your attention to this matter.

Sincerel

Lance V. Junkin Administrator





SunBridge Healthcare Alabama 2020 Garland Court

2020 Garland Court Birmingham, AL 35242

205.991.6667 Fax 205.991.8642 • Gregg.Waycaster@sunh.com

SunBridge
June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To Whom It May Concern::

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Regional Director of Operations for SunBridge facilities in the state of Alabama, where we operate six (6) skilled nursing facilities totaling 755 beds.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At SunBridge we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Respectfully,

Gregg C. Waycaster, B.S., M.A., N.H.A.

Regional Director of Operations

June 28, 2006

Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Cordova Health and Rehab. Cordova Health and Rehab is a 114 bed facility that employees 130 people.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Cordova Health and Rehab, we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely, Anda Daniel

Manatee County Rural Health June 27, 2006



Centers for Medicaid, Medicare Services Department of Health and Human Services P. O. Box 8013 Baltimore, MD 21244-8013

Attn: CMS-1270-P

Re: CMS-1270-P

Dear Sir or Madame:

This letter is in regards to commenting on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation. Imperatively, I strongly object to CMS's alternative proposal that would require beneficiaries to obtain replacement supplies of certain items to (designated providers). This would restrict the beneficiaries choice of where to obtain items. This proposal would severely restrict the beneficiaries access to needed items and supplies. It may also compromise patient health outcomes.

My situation is unique. I work for the Manatee County Rural Health Services, which provides needed medical care to the poor and to the underserved. From my point of view, if beneficiaries are designated to go elsewhere to obtain needed items (DME items), this would severely limit their access to obtain these items. My patients, for the most part are poor and without such amenities such as cars and affordable transportation. Sometimes their only transportation would be on foot, bicycle or bus routes. They have difficulty in getting to the health center to obtain needed medical attention, even when they are critical, i.e. blood pressure out of control, blood glucose 400-500 or ulceration and gangrenous digits. They would have an even greater hardship if they were forced to go elsewhere to obtain needed supplies that could avert some of these medical complications. Our health centers are usually a last resort for those patients that are rejected from the established medical community because of lack of ability to pay. We do not turn anyone away and we provide the needed medical care that they deserve. This proposal would severely compromise my ability to treat my patients in the best possible manner and to avoid unnecessary complications of their condition. This proposal, in my opinion would penalize those that are in most need.

I urge CMS to take steps to insure that small suppliers, which include the majority of pharmacy based suppliers, can participate in the competitive bidding program. As stated above, our health centers do in fact possess their own pharmacies, in which we distribute diabetic supplies, DME items, etc. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible for small suppliers to participate in competitive bidding in large metropolitan areas.

Through our pharmacy and through my particular part of the health care practice at Manatee County Rural Health Systems, we provide diabetic supplies, braces, diabetic shoes, padding, orthotics, wheelchairs, walkers, crutches, etc. These items are most needed in the treatment of the types of patients that come to me in my practice. I have example after example of patients that have been treated in the emergency room, told to follow up with an orthopedic surgeon, that have fractures and dislocations, etc. that have been turned away or that refuse to go to the orthopedic surgeon because that practice requires \$150 up front before they would even be considered to be seen as a patient. These patients do not have the ability to pay. They wind up at Manatee County Rural Health Services so that we can provide the care that they need and deserve. Without these revisions to the final regulation, I will be unable to continue providing valuable services to my patients.

In conclusion, I urge CMS to allow smaller suppliers, such as what I have outlined above with Manatee County Rural Health Systems and other providers that provide needed care to the poor and under served to supply those needed pharmacy based DME items.

Thank you for considering my point of view. I hope to be able to continue to treat my patients in a standard that is not any less of a standard that exists for the rest of the population.

Sincerel

Melvin B. Pace, DPM, PT FACFAS



Manatee County Rural Health Services, Inc. "Taking Care of All Your Healthcare Needs"

21 June 2006

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam

Thank you for allowing me to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments.

I object to the CMS' proposal that would limit the availability of DMEPOS supplies to only those suppliers selected through competitive bidding. The use of designated suppliers limits the beneficiaries ability to obtain supplies. This restricted access may compromise patient health outcomes.

Common DMEPOS supplies such as diabetic testing supplies should not be included in the competitive bidding program. The program should be limited to unique supplies that could be provided by a central supplier.

Small suppliers including pharmacy-based suppliers should be allowed to participate in the competitive bidding program. In addition after a single payment amount for each item has been established, any small supplier willing to accept that payment amount should be allowed to be a contracted supplier.

The proposed regulation needs to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

In conclusion, I urge CMS to revise the regulation to allow Manatee County Rural Health Services, Inc and other small suppliers to participate in the competitive bidding program or to contract to supply these services at the prices established by competitive bidding.

Thank you for your consideration.

Sincerely,

Brian Martin R. Ph. M.S., MBA, M.Ed., C.Ph.

Pharmacy Director

(231)

We're on the Web! www.DenverFoot.com

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P Electronic Comments

We're on the Web! www.DenverDiabeticFoot.net

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

The Medicare/Medicaid patients in this community, especially the diabetic and indigent, rely significantly on the podiatric physician for preventive and management services.

Creating another logistical barrier to necessary and timely care is not the pathway to cost effective health care services.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Athu Sm

Sincerely,

G. Stephen Gill, DPM, MHS, MBA Denver, CO 80110



▶PURPOSE

PROBLEM

PROGRESSION

COMPLICATIONS

TREATMENT

PREVENTION

FOOT WEAR

INSURANCE

LINKS

CONTACT

English or Spanish Click to select desired language

PURPOSE

PREVENTION THROUGH EDUCATION

This website is dedicated to the education - and prevention of foo and ankle complications associated with diabetes mellitus.

Information, illustrations and suggestions will be presented in a manner which avoids complicated medical explanations and recommendations.

Short paragraphs and brief explanations will be used to increase understanding and memory of important foot health information and available treatment options.

When possible, the material will be accompanied by photos illustration or examples that will visually inform and educate.

Links to other diabetic and educational websites will be suggested.

website sponsored by:



Denver Foot and Ankie Clinic, PC Hampden Place Medical Center Rocky Mountain Surgery Center

401 West Hampden, Suite 260 Englewood, CO 80110

> tel. 303 761-5454 fax 303 761-5458 info@denverfoot.com

Please visit and share these websites:



Name: JLMWith DIWNATHED Institution: VNA Of Boston

Write comment below, detach, and mail to To submit feedback via mail: Why implementing Competitive Bidding for diabetes supplies is inadvisable,

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P

PO Box 8013

and why it is advisable to protect small companies like Neighborhood Diabetes:

Baltimore, MD 21244-8013

MUDSE BONUT HOVE TO CORPORATE Relain Month for the Relain of the postmarked!* MALKINE propriet I WORK & Neighborhad Bidacks & strall conputes evenday beforen abel the how to use guishers & test. When I hepe to Wat of my miliets spend spanish & NA New spines Antients for Uhome tenelving with her meks & supplies-Spendicing Unistimetry with some spend tens of my Lefoure Or Neplace Albert dears (fre a value of the LAT () PARY On restricting - if the guineth NEW LAL CARGO

4 DIMATED

Visiting Nurse Association of Boston Southwest Office Hyde Park, MA 02136 130 Bradlee Street

Centers for Medican & Medican Delvices JERT of HENRYL & HUMON DENVICED Rutinosa, MO 21244-8013 4th: CMI-1070-1 1.0. BXX8013

CHANGE OF THE STATE OF THE STAT

Institution: Howe Health MUA-Lawrence Name: Dark S Mrthroun! RU

and why it is advisable to protect small companies like Neighborhood Diabetes: Why implementing Competitive Bidding for diabetes supplies is inadvisable,

Department of Health and Human Services Attention: CMS-1270-P PO Box 8013

Centers for Medicare & Medicaid Services

Write comment below, detach, and mail to

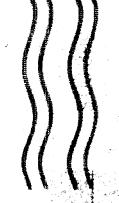
To submit feedback via mail:

Baltimore, MD 21244-8013

making it easy for ats reduces frank and increased complicance Your Sirs- Neighbor hood Dubalies is just as the name implies! Decause Spending more time in the beginning away pin h pennis today and take the long view. They give shoddlest" You't limit us to the cheardest compliance neduces Secula. (MOWN KYON) and ustal ncreased Service

Written comments must be received by June 30th, not just postmarked!

MIDDLESEX-ESSEX



360 Merrimack Street, Building 9, Lawrence, MA 01843

Home Health

Ask for us by name

Centers for Medicue & Medicach Services. Dept of then 141 & Human Services. POBOY SO13 Saldimore MD 21744-8013

CATA CONTRACTOR

Department of Health and Human Services Write comment below, detach, and mail to Centers for Medicare & Medicaid Services To submit feedback via mail: Drew Ru Cos Institution: Half Name: Wand

Why implementing Competitive Bidding for diabetes supplies is inadvisable,

and why it is advisable to protect small companies like Neighborhood Diabetes:

PO Box 8013

Attention: CMS-1270-P

Baltimore, MD 21244-8013

Written comments must be received by June 30th, Not just postmarked!* () The Stand Let Co July and alka 8020 8020 We plucate pateut over a wate guggephalle

26 JUN 2006 PM 11 1 PORTSMOUTH NH 038

• EXETER,

5 ALUMNI DRIVE



inters fr Madian . Madicard Services ept of Health . Herman Sewres 4 2ms. 1270-P Pozox 8013

Institution: GMVDA

and why it is advisable to protect small companies like Neighborhood Diabetes:

Write comment below, detach, and mail to Centers for Medicare & Medicaid Services Department of Health and Human Services Why implementing Competitive Bidding for diabetes supplies is inadvisable,

To submit feedback via mail:

Attention: CMS-1270-P

PO Box 8013

Baltimore, MD 21244-8013

other pervices to

Written comments must be received by June 30th, not just postmarked!



since 1900

Greater Medford VNA & Additional Care

Medford, Massachusetts 02155 278 Mystic Avenue, Suite 204

We partitude of the man Services attention: CMS-1370-P Centers for Medicare a Medicaid Services Battone, 46 21244-8013

COM OTOMETANIA

hille Helle Helle

Name: Mar Powers Institution: VNA of

and why it is advisable to protect small companies like Neighborhood Diabetes: Why implementing Competitive Bidding for diabetes supplies is inadvisable,

Write comment below, detach, and mail to Centers for Medicare & Medicaid Services Department of Health and Human Services

To submit feedback via mail:

Attention: CMS-1270-P PO Box 8013

Baltimore, MD 21244-8013

Complicate e need (letahborhood **ペノしの**ク

Written comments must be received by June 30th, not just postmarked!



. بروسر

Southwest Office 130 Bradlee Street Hyde Park, MA 02136 Lester For Medicare a Medicard Services beport ment of Health and Human Services LING-MOIE AN JOMITHONIS AHNO CMS-1270-P RUBOR 1013

日本の のいる十をからの

Pine Creek Podialry

(234)

WILLIAM J. SCHLORFF, DPM, F.A.C.F.A.S. PODIATRIC MEDICINE & FOOT SURGERY

BOARD CERTIFIED
AMERICAN BOARD OF PODIATRIC SURGERY
MEMBER OF
AMERICAN COLLEGE OF FOOT AND ANKLE SURGEONS

345 EAST CENTRAL AVENUE JERSEY SHORE, PA 17740 TELEPHONE (570) 753-4335

Monday, June 26, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Dept. of Health and Human Services Attn. CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Dr. McClellan.

I am writing to urge the CMS to revise the physician definition from 1861(r)(1) to 1861(r)(3) in the proposed rule that would establish a competitive acquisition program for durable medical equipment, prosthetics, orthotics and supplies(DMEPOS).

As a podiatric physician, I both prescribe and dispense DMEPOS items to Medicare patients as an important adjunct to my patients care. As their provider of foot care I feel that I am the physician most qualified to both prescribe and dispense the appropriate device to suit my patient's conditions. Years earlier, prior to obtaining a DME license, I had to use several different DME suppliers. This proved to be a fiasco for my patients as they would obtain either the wrong device or a much poorer quality device which did address their condition properly.

If the physician definition 1861(r)(1) is implemented it will have a negative impact on my patients and my ability to offer them quality care. Therefore I strongly urge you to modify the physician definition to 1861(r)(3)

Sincerely

William J. Schlorff, DPN

To: Centers for Medicare / Medicard Serv Re: Proposal in Section 414.15 -Low Vision aid Explusion

Please do NOT bar Medicare

Soverage for devices Duch as

CCTV System, maginfiers, or other

Kow Vision Aids or technologies!

My mother is legally blind due to macular degeneration. These aids) are vital to her quality of life! Darah Shiply, tem # 2071000 for Hally Randolph

(239)

Docket Management Comment Form

Docket: CMS-1270-P - Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Temporary Comment Number: 85477

Submitter:	
Dr. Joseph Grillo	Date: 06/28/06
Organization: American Podiatric Medical Association	
Category: Physician	
Issue Areas/Comments	
Quality Standards and Accreditation for Supplies of DMEPOS Quality Standards and Accreditation for Supplies of DMEPOS	
Dr McClellan, Podiatrists ARE physicians and to classify them as otherwise is ridiculous. We admit patients, perform surgery and DAILY prescribe shoes, orthotics and other durable medical equipment and to exclude as physicians is predjudicial and an insult to myself and my patients. All this is is another assault on patient rights. Imagine if you walked into your doctors office, had a fracture or Charcot joint and had to go to another provider to get what you need to get better. I firmly oppose CMS attempt to put this up for contractual bidding and predjudicial exclusion of podiatrists from taking care of patients as we know best how to do. Sincerely, Joseph Grillo DPM-Ft. Myers, FL	
Attachments	
No Attachments	
Print	Comment on Another Docket Exit
	Print - Print the comment

Exit - Leave the application





June 29, 2006

Kathleen M. Stone, D.P.M. Teisha L. Chiarelli, D.P.M.

Mark B. McClellan, M.D., PhD. Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services P O Box 8013 Baltimore, Maryland 21244-8013

Attention: CMS-1270-P Electronic Comments

Dear Doctor McClellan:

I am writing to you regarding the Centers for Medicare and Medicaid Services' (CMS) proposal with respect to the new competitive acquisition program for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). I believe this would be extremely detrimental to my Medicare population of patients if approved as currently proposed to provide the best quality and medically necessary care. I am requesting you consider excluding all physicians, including podiatric physicians, from this proposal.

I see Medicare patients on a regular basis in my 10-year old podiatric practice in the Phoenix metropolitan area. I am currently able to provide these patients with the best possible care in an efficient manner with respect to DME supplies, such as Cam walkers and braces, for various acute injuries and fractures. I understand CMS is still in its decision making process with respect to this proposal but do believe this could be detrimental and even harmful to my Medicare population should I no longer be able to provide this care.

In closing, I do hope that you and CMS as a whole are willing to reconsider excluding all physicians including podiatric physicians, from this competitive acquisition program. It is my hope that we as physicians are allowed to continue being DMEPO suppliers within our offices to provide the best possible care for our Medicare population.

Thank you for your consideration.

Sincerely,

Teisha L. Chiarelli, D.P.M. tlc@thunderbirdfootcare.com

TLC:hw:61306





June 30, 2006

RE: Competitive Bidding Comments Submittal: www.cms.hhs.gov/eRulemaking

Centers for Medicare & Medicaid Services, Department of Health & Human Services ATTN: CMS-1270-P PO Box 8013 Baltimore, MD. 21244-8013

To Whom It May Concern:

As a DME provider, we are aware that the process of competitive bidding is inevitable. However, there is not enough clarity on the entire process in order for us to move forward in such a short period of time with such drastic changes that may effect not only a small business such as ours, but clients and patients who are dependant upon medical equipment and supplies. It is to our understanding that CMS intends on selecting items for the competitive bidding process that contain the highest cost and highest volume. We believe that this proposal poses a problem for those patients in urgent need of wheelchairs, hospital beds, patient lifts, oxygen supplies, diabetic testing supplies, etc. These supplies are vital to the physical condition of our clients.

Although we are already accredited by the Exemplary Provider Accreditation Program and remain in good standing with Medicare and are in respectable financial standing with our creditors; we are concerned about the jeopardy of our "small business". The fact, that Medicare proposes the idea of examining two years of past claims for each item on a monthly basis to determine the expected demand vs. how many suppliers are needed to meet the projected demand, is a major concern as a determining factor. To explain, we have been in business for almost 10 years and we are a growing company. The suppliers and clients that we have today are not comparable to what we had even in the past two years. If these determining factors abide, it seems as though the bigger corporations will "knock us out of the box", altogether.

According to the demographics described by CMS, New York, Los Angelos, & Chicago will be excluded from competitive bidding. Our office is located in New Lenox, IL approximately 30 miles outside of Chicago and we are unclear how this will affect our

company. Thus, a more thorough scrutiny and explanation of what "Competitive Bidding" entails is considered necessary in keeping us abreast as a small business.

Conclusively, in addressing the power mobility rule... physicians will have 45 days instead of 30 to provide us with a prescription and supporting documentation after a face-to-face exam with the patient. This rule affects the patient significantly because, in most cases, doctors hardly ever submit this information to us in a timely matter. We call repeatedly and these physicians "drag their feet". Our primary concern, must meet the needs of our patients/clients first and foremost. We must **NOT** cut corners with our client's health. It is our fiduciary duty to provide them with the best quality care possible. How are DME providers, such as our organization, able uphold our duty if we cannot afford to compete with the mass corporations? On behalf of our company, we trust that our concerns will be taken into careful consideration. Please do not hesitate to contact us, if you have any questions or concerns.

Respectfully submitted,

Sheba L. Wilburn, Admin. Asst.

Accounting Department



MARK A. ALDRICH, D.P.M., F.A.C.F.A.S.



CERTIFIED BY THE AMERICAN BOARD OF PODIATRIC SURGERY June 27, 2006

Mr. Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services.
Department of Health and Human Services
Attn: CMS-1270-P
P. O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan and Those Concerned:

I am writing to you to express my opposition to the proposed rule establishing a competitive bidding program for certain durable medical equipment including prosthetics, orthotics and supplies including diabetic shoes (DMEPOS).

Competitive bidding would only allow provision of durable medical equipment by the largest suppliers and providers, who of course could make the lowest bids. Those like myself, who practice in rural areas would not be able to compete on a cost-bidding basis and therefore would not be able to supply such services including diabetic shoes to our patients.

Not only would my many diabetic patients be affected, but any of those individuals who need immobilization for sprains, fractures and the like, as I would again not be able to provide bracing or AFO's for them, because I could not compete with the larger suppliers.

This bidding proposal would affect all small practices including podiatrists and all physicians in a small practice situation. If I am no longer able to supply these services to my patients, they are the ones who ultimately suffer having to travel to get such services.

Therefore, I request that the centers for Medicare and Medicaid services <u>exclude</u> physicians including podiatric physicians from the new competitive acquisition program for durable medical equipment including prosthetics, orthotics and supplies.

As a podiatric physician practicing for more than 22 years, I have a clear understanding of what the recent competitive acquisition will do and the detrimental effect it will have on patient care provided through my office.

Thank you for your time and consideration in this matter.

Respectively Submitted,

Mark A. Aldrich, D.P.M.

MAA/la



Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013



Re: Competitive Bidding

To Whom It May Concern:

Recently, there have been some changes to CMS guidelines and formulations regarding certain MSAs. Herein, NPWT will most likely be considered as an entity up for competitive bidding. As a plastic and reconstructive surgeon, I feel that this is a crucial issue and fear that if a "bidding war" comes about there will be a sacrifice in quality and result in a compromise in patient care. Negative pressure wound therapy is at the heart of my practice and is a mainstay for the thousands of wounds I treat every year. There are certain scientific elements that exist with negative pressure wound therapy (VAC therapy from KCI) and if the use of a device goes to the "cheaper" product (Versatile 1 from Blue Sky) based on price we may compromise patient care and subsequent outcomes (i.e. osteomyelitis, amputations, sepsis and major reconstructive surgical procedures). The Versatile 1 equates to longer hospitalizations, longer use of the cheaper product, multiplication of ancillary services and increased use of antibiotics which will lead to increase in bacterial resistance thus repeating the cycle.

My argument is not to promote "expensive" care, rather quality care that has proven the test of time. In my extensive experience I have yet to encounter a device that is comparable to the original VAC system and towards that end others may imitate but will never equal the original negative pressure wound therapy product.

I have worked with negative pressure wound therapy devices for approximately ten years and through the years it has changed my thought process and further changed the way thousands of plastic and reconstructive surgeons practice their art. We perform far less major reconstructive procedures because negative pressure wound therapy promotes healing with a decreased need for hospitalization thereby reducing costs.

In conclusion, I request that you consider a no competitive bidding effort toward negative pressure wound therapy and suggest that you inquire about the use of negative pressure wound therapy and ALL its applications before pursuing this matter further. I would like to thank you for giving me the opportunity to provide this important information for your review.

Respectfully submitted;

Vipul R. Dev, M.D.





Dr. Charles S. Yeager Dr. Thomas M. Herrmann Dr. Steven W. Kreamer Dr. Peter J. Fodor Dr. Melissa A. Cavallaro

Podiatric Medicine, Sports Medicine, Foot & Ankle Surgery

June 15, 2006

Centers for Medicare and Medicaid Services

RE: Proposed Rule Regarding Establishment of Competitive Acquisition Program For Durable Medical Equipment (DMEPOS)

To Whom It May Concern:

I am writing this letter in behalf of our practice regarding the proposed rule by which physicians' offices, as well as other suppliers of durable medical equipment, would need to compete for the ability to provide these materials to patients at our practice. It is my understanding that we would need to compete with all suppliers and that it is possible, if our bid was not accepted, that we would not be able to provide these services for our patients.

I have a significant concern about this as with the current setup we are able to customize our shoes to patients' needs. It has been my experience in the past with some other non-Medicare insurances that when we provided these services outside the office it was difficult to coordinate both fabrication and adjustment of these shoes and other devices. As a result, there were times when patients had irritation of certain areas and even ulcerations which required further treatment and cost, both to the patient and to the insurance company.

In reviewing research I understand that there are approxiamtely 7,300 podiatric physicians who have DMEPOS supplier numbers across the country. Of this number of physicians, they are responsible for only 3.1% of the DMEPOS allowed charges. This would seem to indicate that a very small percentage of the actual monies which are spent on these devices go to physician offices. Although I have no hard data, I would also suspect from what we have seen in our area in Lancaster, Pennsylvania that the shoes and other devices provided through the office are actually cheaper than those provided by the larger suppliers.

I also believe that with the small monetary percentage of payment to physicians that this would more than offset the potential additional treatments that may be required through inappropriate or inadequate shoes or modifications. I find that it is always easier for one person to deal with both the modification of orthotic devices and shoes and treating the patient as this can be coordinated in a much more streamlined manner.

If you have any questions, please feel free to forward any additional concerns to me, but I would greatly appreciate it if you would consider this opinion prior to passing your proposed rule which I believe would be a concern for many patients, as well as physicians.

Sincerely,

Thomas M. Herrmann, DPM FACFAS

TMH/1b

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230 PH (804)285-8055 FAX (804)285-8059



June 22, 2006

Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Areas

Mail Order Competitive Acquisition Program

I strongly object to the proposal that would require beneficiaries to receive refills by mail order. Patients come to rely on their local pharmacist for questions and assistance. Loss of human contact would mean losing the opportunity for counseling. A bulk mail order program would never notice if a patient was not properly using their medication, or recommend another doctor visit if the patient's health declines. Often a pharmacy is the one place where the patient's care from multiple doctors comes together. Losing this would mean diminishing patient care.

Additionally, patient flexibility would be lost. There will be a reduction in available suppliers, particularly small providers, following the accreditation requirements. Further reducing the available suppliers by competitive bidding for items such as diabetic supplies would make it more difficult for diabetic patients to obtain their testing supplies. This is certainly not an area where we would want to make supplies hard to obtain. Monitoring blood sugar levels is key to diabetic patients maintaining a healthy lifestyle. Mailing a product takes days, local pharmacies can provide same day product delivery. As stated, losing flexibility could cause a decline in compliance to the doctor's orders. Creating a mail order program that would automatically replace items would not only increase the cost but would also violate the supplier standards established by Medicare. Patients should be given the option to go where they want to purchase their supplies when they are needed and not be forced to use what could be a confusing and long process.

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230 PH (804)285-8055 FAX (804)285-8059

Criteria for item selection

The competitive bidding program should not select diabetic supplies for bidding. Diabetes is a complicated and dangerous disease to have. It should be monitored by professionals who will take the time to educate their patients and not by the location willing to sell for the least. Quality of care should play a factor in this process.

Determining single payment amounts

Determining cost by bids may give an unfair advantage to larger companies who are able to purchase in bulk. The average wholesale price for the item should be considered as well as the amount bid. If the bid is for less than what the average wholesaler can afford to sell a product line, again the number of available locations would be severely limited and small suppliers would be unable to participate. Inclusion of small suppliers should be considered when establishing the process.

Setting the rate as the median bid, then increasing by the consumer product index during the second and third years does not account for increases in acquisition rates. If the reimbursement rate becomes less than the cost of purchase for the item, suppliers will not be able to continue providing this product and stay in business. Ongoing availability should be considered when establishing the process.

Rebates offered by suppliers who could offer the product for less would give an unfair advantage to larger suppliers who can purchase items in bulk. If suppliers are permitted to advertise their rebate offers small suppliers may lose business to larger companies based on price and again be left out of this process.

Opportunity For Participation by Small Suppliers

Small suppliers, which include the majority of pharmacy-based suppliers, will not have the ability to participate if the only distinguishing factor is the product line. Many larger suppliers participating in the DMEPOS program carry all types of products. Independent pharmacies would be forced to compete with larger chains that are able to purchase items at a discounted rate.

Small suppliers should be given the opportunity to accept the single payment amount and join the competitive bidding program as a contracted supplier. I believe this should be done to preserve a population of small suppliers available to the Medicare DMEPOS community. If small suppliers could be pooled in a separate bidding process than the larger companies, the difference in rates could be evaluated to determine a fair reimbursement amount.

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230 PH (804)285-8055 FAX (804)285-8059

Our company owns three independent pharmacies. We carry ostomy supplies, diabetic, supplies, supports and braces, immunosuppressive drugs, and nebulizer medications. Without these revisions and considerations, we will be unable to continue to provide these services for our patients, many of who have been our patient's for the last 30 years.

In conclusion, I urge CMS to abandon the mail order concept and leave the products with the local suppliers, to eliminate items such as diabetic supplies from the competitive bidding process, to ensure there is an even playing field by considering more than product type as a way to include small suppliers, to allow the average wholesale price of a product line play a factor in the approved amount for bid, to review and update the reimbursement rate yearly based on the acquisition cost, and perhaps give small suppliers the opportunity to bid in a separate grouping to even the playing field.

Thank you for considering my view.

Sincerely,

Wendy Herbert Richmond Apothecaries Program Manager 2002 Staples Mill Road Richmond, VA 23230 (804)285-8055 ext 114





2600 S. Raney Effingham Illinois 62401

Phone: (217) 342-3412 (USA Only) (800) 879-0117

Fax: (217) 342-3384 www.jointactivesystems.com

June 30, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics,

Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

We are Joint Active Systems, Inc. (JAS). We are an Illinois corporation and currently employ about 70 workers. In addition, more than 160 individuals in other States work for JAS throughout the country. We manufacture clinically-proven, patented, static progressive stretch devices/orthosis used to treat restricted range of motion in the shoulder, elbow, wrist, forearm pronation/supination, knee, ankle, and finger joints secondary to trauma, surgery, immobilization, burns, or neurologic injury. More importantly, we have enrolled in the Medicare Program for the sole purpose of supplying and billing only the devices that we manufacture. JAS requested and obtained the following Healthcare Common Procedure Coding System (HCPCS) codes for its devices: E1801, E1806, E1811, E1816, E1818, and E1841. We respectfully submit our comments to the proposed rule regarding the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), which was released on May 1, 2006 (71 Fed. Reg. 25654).

1. General Comments

We strongly urge the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the competitive acquisition program (CAP) for DMEPOS items until the Supplier Quality Standards (Quality Standards) are finalized and released by CMS. CMS must not require suppliers to make a competitive bid on any DMEPOS item without affording them the opportunity to be informed about the additional cost that they must incur in order to comply with the new Quality Standards. The benefits of true competition as Congress intended can only be realized if the suppliers have all of the facts that are necessary to make informed bids.

As you know, even the Program Advisory and Oversight Committee (PAOC) recommended that CMS delay the CAP until the Quality Standards are made available to the suppliers, especially given that, according to CMS, significant revisions have been made to the draft Quality Standards that were introduced on September 26, 2005. Furthermore, CMS has stated that it would release the final version of the Quality Standards in June of 2006. To date, CMS has not done so. Therefore, JAS requests that CMS accept the recommendation of the PAOC.

2. Criteria for Item Selection

If an entity that is the sole manufacturer and supplier of a particular DMEPOS item is unable to bid or participate in CAP, then the Medicare Program has effectively eliminated access to this DMEPOS item by the beneficiaries. This clearly is not the intent of Congress. Therefore, CMS must exempt such manufacturer-suppliers from the proposed requirement that all suppliers bid for all items in a particular product category to be finalized and announced by CMS. Instead, in order to protect each beneficiary's access to such single-source DMEPOS items, manufacturers like JAS that supply only those DMEPOS items that they manufacture should be afforded the same exemption proposed for skilled nursing facilities (SNFs) and physicians. Like SNFs and physicians providing DMEPOS items only to their patients, manufacturer-suppliers are not "commercial suppliers" because they do not supply every DMEPOS item reimbursable by the Medicare Program.

Alternatively, CMS should phase in such single-source DMEPOS items and manufacturer-suppliers after 2009. Delaying the inclusion of such items and suppliers will allow CMS to not only learn about the effects of CAP in general but also address the unique issues of single-source DMEPOS items and manufacturer-suppliers in particular. Likewise, CMS must designate the product categories narrowly. CMS must permit suppliers to bid for those DMEPOS items that only they can supply. By requiring suppliers to bid for every DMEPOS item in a product category, CMS would hinder true competition and fail to assure the most savings because the one manufacturer-supplier that could provide the lowest bid would actually not be able to bid because it only supplies those DMEPOS items that it manufactures.

In addition, CMS must comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and actually "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must seriously consider excluding from CAP those DMEPOS items that are supplied only by the manufacturer. Congress did not intend CAP to prevent Medicare beneficiaries from accessing DMEPOS items that CMS has coded and has been reimbursing prior to either the enactment of the Medicare Modernization Act of 2003, which mandated the CAP, or the implementation of CAP itself.

3. Submission of Bids under the Competitive Bidding Program

CMS must only apply CAP to "commercial suppliers." Just as CMS realized that SNFs and physicians are not "commercial suppliers," CMS must understand and acknowledge that manufacturers that only supply the DMEPOS items that they manufacturer are not "commercial suppliers." While SNFs and physicians supply the full range of DMEPOS items only to their patients, manufacturer-suppliers supply only those DMEPOS items that they manufacture. Therefore, because of the limited type of DMEPOS items that such manufacturer-suppliers provide

to Medicare beneficiaries, they are less of "commercial suppliers" than even the SNFs and physicians supplying every type and quantity of DMEPOS items.

Again, CMS must designate the product categories narrowly. CMS simply must permit suppliers to bid for those DMEPOS items that only they can supply. It is not only logical but also beneficial to the Medicare beneficiaries. For JAS, it would be particularly ironic if it could not bid or participate in CAP. In 2005, JAS met with CMS (Joel Kaiser and a few DME Regional Carrier medical directors) to discuss the pricing of the codes for its devices that JAS has requested and obtained through the HCPCS coding process. CMS has not yet responded to the request to increase the reimbursement rates. Now, JAS is struggling with the painful requirement that all bids must be lower than the current Medicare rates. It would indeed be a slap in the face if CMS were to deny JAS, the sole supplier of the devices that it manufacturers, the opportunity to even bid because CMS defined the product categories broadly. Most importantly, the Medicare beneficiaries would be denied access to these clinically effective and cost efficient devices, which require 3 months of wear-time on average and not the 15 (now 13) months permitted by CMS.

4. Conditions for Awarding Contracts

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

5. Opportunity for Participation by Small Suppliers

CMS must consider the small manufacturers like JAS that have enrolled in the Medicare program only to be able to supply the DMEPOS items that they manufacture. These manufacturers have accepted this course, despite the risk of being subject to various additional Medicare restrictions (e.g., Stark self-referral prohibitions), because they have experienced problems merely selling their DMEPOS items to Medicare "commercial suppliers." They want to ensure that their DMEPOS items are properly delivered to, fitted by, and used by the Medicare beneficiaries. CMS must not penalize such manufacturer-suppliers.

Section 1847(b)(6)(D) addresses the "protection" of small suppliers and not just the identification of such suppliers. Therefore, CMS must treat small suppliers differently. Manufacturers that only supply the DMEPOS items that they manufacture are not "commercial suppliers" that supply the full and complete list of DMEPOS items. CMS must actively help small suppliers, including manufacturer-suppliers, so that they may participate in CAP and provide the Medicare beneficiaries access to such single-source DMEPOS items.

6. Opportunity for Networks

CMS must provide sufficient time for suppliers to establish and work collaborative in the networks permitted by CMS under the proposed rule if CMS truly wishes to allow suppliers to form networks in order to bid competitively. CMS must not erroneously believe that the potential for volume is the motivating factor for the suppliers. Instead, CMS must realize and accept the fact that suppliers want to and need to bid and participate in CAP to merely stay in the Medicare program.

7. Quality Standards and Accreditation

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

On behalf of over 230 hard-working families of JAS, we thank you for the opportunity to comment on the proposed CAP for DMEPOS items. We hope that CMS will truly consider each of our comments.

Sincerely,

Dean Kremer

President

cc: Sandra Bastinelli (via e-mail)

D. W.

Carol Blackford (via e-mail)

Stacy Coggeshall (via e-mail)

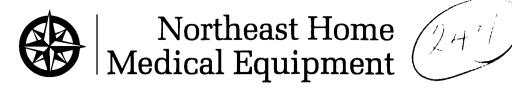
Joel Kaiser (via e-mail)

Martha Kuespert (via é-mail)

Herb Kuhn (via e-mail)

Walt Rutemueller (via e-mail)

Linda Smith (via e-mail)





60 Cohoes Avenue Green Island, NY 12183 (518) 271-9600 fax (518) 271-3816 www.NortheastHealth.com

Mark B. McClellon, MD PhD. Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

Dear Dr. McClellon:

We are writing to provide comments on Competitive Acquisition for Durable Medical Equipment proposed rule CMS-1270-P and its impact to patients and providers.

In way of background, Northeast Home Medical Equipment is a not for profit oxygen and durable medical equipment provider in Upstate New York. We are part of Northeast Health, a not for profit integrated network employing over 4,000 people and serving a 15-county area. Services include acute care, supportive housing and community services, skilled nursing care, home health care and independent retirement living.

Comments Regarding the Notice of Proposed Rule Making (NPRM):

- "General"- Getting It Right Is More Important Than Rushing Implementation. CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Additionally under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates the option for small providers to participate.
- "General"-CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulations; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. We believe that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.
- "General"- The Program Advisory And Oversight Committee (PAOC) Must Be Included 3.) By CMS In The Review Of Public Comments And The Development Of The Final Rule.

CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC.

- 4.) "Quality Standards and Accreditation for Suppliers of DMEPOS"- Only Companies That Are Accredited Should Be Eligible To Bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.
- 5.) "Conditions for Awarding Contracts"- An Appropriate Screening Process Must Be

 Developed To Determine Which Submitted Bids Will Qualify For Consideration.

 (proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.
- 6.) "Conditions for Awarding Contracts"- Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.
- 7.) "Competitive Bidding Areas"- <u>Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries</u>. The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done.
- 8.) "Criteria for Item Selection"- Product Selection Must Be Conducted With Beneficiary Welfare In Mind. (Criteria for Item Selection) How will "savings" be calculated; exempt items and services unless savings of at least 10 percent can be demonstrated as compared to the fee schedule in effect January 1, 2006; recognize problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented that should not be competitively bid.

- 9.) "Criteria for Item Selection"- Consider The Impact On The Patient. CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.
- 10.) "Determining Single Payment Amounts for Individual Items"- Rebate Provisions Must Be Eliminated. (proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.
- 11.) "Submission of Bids Under the Competitive Bidding Program"- Only Companies Currently Delivering Service To Medicare Beneficiaries In An MSA Should Be Allowed To Submit A Bid For That MSA. Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record.
- 12.) "Conditions for Awarding Contracts"- <u>Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts</u>. (proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.
- 13.) "Conditions for Awarding Contracts"- <u>Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid.</u> (proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.
- 14.) "Conditions for Awarding Contracts"- A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "compilation", "review", or "audit" report from an independent Certified Public Accountant. (b.) Certificate of Insurance verifying a minimum of \$1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from a recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Debt to Equity Ratio" and "Current Assets to Current Liabilities".

- 15.) "Conditions for Awarding Contracts"- <u>Use A Factor Of 130% In Calculating Supplier Capacity Needed In An MSA</u>. (proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payers, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.
- 16.) "Conditions for Awarding Contracts"- <u>Safeguards Must Be Put In Place To Ensure Realistic</u>
 "Capacity" Amounts Are Assigned To Bidding Companies. (proposed §414.414(e))
 Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of units provided to Medicare beneficiaries the previous year.
- 17.) "Conditions for Awarding Contracts"- A Company Should Be Able To Bid For Only A Portion Of An MSA. The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.
- 18.) "Conditions for Awarding Contracts"- Do Not Restrict Submitted Bid Amounts. (proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical needs.
- 19.) "Terms of Contract"- Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (proposed §414.422(c)) The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these costs into their bids.

- 20.) "Terms of Contract"- Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated. (proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.
- 21.) "Terms of Contract"- <u>Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier</u>. (proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.
- 22.) "Opportunity for Participation by Small Suppliers"- Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers. ("Opportunity for Participation by Small Suppliers) At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.
- 23.) "Opportunity for Networks"- <u>Clarify Network Regulations.</u> (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?
- 24.) "Opportunity for Networks"- <u>Do Not Place Unreasonable Limitations On Formation Of Networks</u>. (proposed §414.418) The 20% market share limitation should be removed. This is unnecessarily restrictive and does not apply to single entities that bid separately. Network members should be able to also bid as an individual entity.
- 25.) "Payment Basis"- Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables. (proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in non-bid area, CMS should pay the traditional Medicare

1020 First Avenue PO Box 61501 King of Prussia, PA 19406-0901 Tel: 610-878-4583 www.zlbbehring.com



ZLB Behring

June 26, 2006

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Post Office Box 8013 Baltimore, MD 21244-8013

ATTN: (CMS-1270-P) Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics which include intravenous immune globulin (IVIG), used for treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha₁-proteinase inhibitor, used to treat alpha₁-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created through the pooling and manufacturing of donated human blood plasma or through the development of recombinant DNA technology.

Most recently, ZLB Behring launched a new therapy, a subcutaneous immune globulin (SCIG) under the brand name Vivaglobin, used specifically for the treatment of primary immune deficiency. Vivaglobin, which was approved by the Food and Drug Administration in late 2005, represents an advance in treatment and quality of life for patients. Infusions can now take place in the home, instead of a hospital setting; infusions will no longer last several hours in duration; and the response rate is greater with far less adverse reaction potential.

Vivaglobin will be administered through an infusion pump, qualifying the therapy for reimbursement under the Part B durable medical equipment (DME) provisions. In April of 2006, CMS preliminarily approved a HCPCS code for SCIG and there was no public opposition at the May 11, 2006 HCPCS public meeting where this application was discussed.

ZLB Behring requests that CMS exclude this innovative new therapy from the proposed competitive bidding regime applicable to certain durable medical equipment, prosthetics, orthotics and supplies. We believe that prior agency history with respect to IVIG can and should serve as a precedent for the treatment of SCIG in the future.

In particular we believe that CMS should exclude SCIG from the DMEPOS competitive bidding program in the same manner in which it excluded its predecessor therapy, IVIG, from the Part B drug competitive acquisition program (CAP). Excluding SCIG from the DMEPOS competitive bidding program is consistent with previous CMS precedent and the Congressional intent to exclude immune globulin in its intravenous method from the CAP.

Precedent set by Congress and CMS for a Broad Immune Globulin Exception

When Congress passed the Medicare Modernization Act (MMA) of 2003 creating the CAP it specifically excluded IVIG from the program (Public Law 108-173, Section 303, (b)(1)(E)(ii)). For its part, CMS recognized the uniqueness of immune globulin by acknowledging in the final rule implementing the CAP that IVIG, in addition to other forms of immune globulins, such as those administered intramuscularly would also not be excluded from the CAP. Moreover, other blood-plasma therapies such as blood clotting factors and alpha₁-proteinase inhibitor were also deliberately excluded from CAP.

SCIG was not yet approved at the time of MMA's consideration and was not available to patients, thus exclusion from the DMEPOS competitive bidding portion of the MMA legislation was not addressed. However, we believe Congress' action in excluding IVIG from CAP should apply to all forms of immune globulin from all varieties of competitive acquisition programs and should not be limited by the methods of administration. The precedent and intent is for the exclusion of immune globulin from the program and not the specific form of administration.

SCIG will treat Medicare beneficiaries with Primary Immune Deficiency, just as IVIG

SCIG is a treatment for a subset of patients who currently use IVIG. SCIG is indicated solely for the treatment of patients with Primary Immune Deficiency whereas IVIG is indicated for Primary Immune Deficiency in addition to other conditions, depending on the individual brand. SCIG may be particularly appropriate to treat those individuals with poor venous access (a detriment to intravenous use of immune globulin), and those who have developed adverse reactions to IVIG. For those reasons and others, we anticipate that many patients with primary immune deficiency may wish to migrate over time to SCIG.

Access to therapy is greater when excluded from CAP

Excluding most immune globulins from CAP but including the subcutaneous form of therapy in the competitive bidding program for DMEPOS would disadvantage and discourage access to a new and improved approach in treatment that will benefit segments of the immune deficient population. As more SCIG brands are approved and placed into the HCPCS code, the DMEPOS competitive bidding program could result in some therapies in the class not being covered. Such a situation could exacerbate ongoing patient access issues with immune globulin.

Vivaglobin specifically will provide some relief to the pressing IVIG access situation, as it is a new source of therapy manufactured from a different facility than ZLB Behring's existing brand of IVIG. However, if SCIG is incorporated into the competitive bidding program for DMEPOS, the likelihood of multiple brands being available for a small patient population (estimates are that less than 10,000 patients are Medicare beneficiaries) is diminished, thus deterring patient access to this therapy. It is this logic that led Congress to exempt IVIG from the CAP. We believe that logic should be extended to the other immune globulins, like SCIG, as well.

Manufacturers of plasma therapeutics are unlike those in the pharmaceutical or medical equipment sectors. Manufacturing life-saving therapies from human blood plasma require high material and manufacturing costs. Today, only a few manufacturers provide therapies for a small population of patients with serious genetic disorders. We believe a rational, consistent payment policy that excludes all forms of immune globulin from all varieties of competitive bidding regimes is the best way to accurately reimburse providers and ensure a stable supply of therapies.

Conclusions

Historically, CMS has shown sensitivity to the needs of patients reliant on blood-plasma therapies such as immune globulin by excluding such therapies from competitive bidding programs. We believe similar treatment should extend to the competitive bidding program for DMEPOS with respect to SCIG. While a competitive bidding program may be appropriate for durable medical equipment or other Part B drugs, we believe it is inappropriate for plasma therapies like immune globulins that treat serious rare diseases and chronic conditions. ZLB Behring believes that CMS should apply a broad exclusion to all immune globulins, regardless of administration method, from all competitive bidding programs.

ZLB Behring would be very happy to meet with you and/or professional staff from the durable medical equipment program to discuss in greater detail. You are welcome to contact Patrick Collins at 610-878-4311 or myself if we may be of any assistance or answer questions. Thank you for your consideration and we appreciate CMS efforts to date in recognizing the uniqueness of immune globulins and the patients who rely on this therapy.

Sincerely,

Dennis Jackman Senior Vice President, Public Affairs

Tennessee Pharmacists Association

500 Church Street, Suite 650 \cdot Nashville, Tennessee 37219

Phone: 615/256-3023 tpa@tnpharm.org

Fax: 615/255-3528 www.tnpharm.org



June 23, 2006

Centers for Medicare & Medicaid services Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

On behalf of pharmacists in all practice settings in Tennessee and the patients they serve, the Tennessee Pharmacists Association (TPA) appreciates the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. We offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Access

TPA urges CMS to develop the competitive bidding program in such a manner as to ensure beneficiaries' continued access to needed items from the provider of their choice. TPA urges CMS to not implement the CMS alternate proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. This proposal could severely restrict beneficiaries' access to needed items and supplies. Restricting beneficiaries' access to mandatory mail service only is not appropriate for DME such as diabetic testing supplies, including lancets and glucose testing strips, and, also, ostomy supplies, items to which beneficiaries need convenient and frequent access. Beneficiaries also frequently need hands-on, face-to-face education and assistance in use of these items. In addition, ostomy patients require immediate and convenient access to the supplies they need. Ostomy patients frequently develop problems requiring an immediate change in ostomy appliances and supplies being used. These problems include the development of allergies to the products being used, a change in the ostomy opening requiring either a temporary or permanent change in the size of the product being used, or a change in output requiring the patient to obtain additional supplies. In these instances, patients need to be able to obtain supplies and assistance from a local provider. TPA also urges CMS to exercise its authority to exempt from this process those rural areas with low population density in particular. If this is not done, beneficiaries will be at risk of having their access restricted. Beneficiaries value their established provider/patient relationships, and CMS should take steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain these provider/patient relationships.

Criteria for Item Selection

TPA recommends that the competitive bidding program not include common DMEPOS supplies such as diabetic testing supplies. TPA believes CMS should limit the competitive bidding program to those unique products that could be provided by a central supplier and for which beneficiaries will not need ongoing, face-to-face education and assistance to use. Diabetic testing supplies were not included in either of the two competitive bidding demonstrations in Florida and Texas.

Determining Single Payment Amounts

While TPA understands that CMS is required to set a single payment amount for each item, we are concerned that using the median bid will set an artificially low payment rate that many small suppliers, such as community pharmacies, will not be able to accept. CMS must review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier's costs to acquire and provide the product. CMS must periodically examine the payment rate as it compares to supplier acquisition costs. Obviously, there is no increase in volume that can make up for a loss on items that are being provided and reimbursed below cost.

TPA recommends CMS reconsider its intention to update the single payment rate based on the consumer product index during the second and third years of the supplier contract. This proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. Under the current CMS proposal, providers would be required to continue providing the product at the single payment rate, even if the reimbursement amount is significantly less than their acquisition cost. Suppliers will not be able to continue providing DMEPOS supplies when they are being reimbursed below their acquisition cost. CMS must make provisions for re-evaluation and adjustment of payment amounts during the year, if acquisition costs change.

Participation by Small Suppliers

TPA urges CMS to take steps to ensure that small suppliers, which include the majority of pharmacy-based suppliers, can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to compete in a larger competitive bidding area.

CMS should make every effort to streamline the competitive bidding process. A complex, time-consuming bidding process will seriously hamper the ability of small community pharmacy providers to participate in the process. The CMS estimated cost of \$2,187 for submitting a bid will be cost-prohibitive for many of the smaller rural community pharmacy providers in our state. Because of this barrier to participation, after

CMS establishes the single payment amount for each item of DMEPOS, any smaller supplier willing to accept the payment should also be allowed to join the competitive bidding program as a contracted supplier.

TPA urges CMS to take these steps to preserve beneficiaries' convenient access to quality DMEPOS supplies and related services and to maintain established provider/patient relationships.

Thank you for your consideration of the views of the Tennessee Pharmacists Association on behalf of our members who serve Medicare beneficiaries every day.

Sincerely,

Baeteena M. Black, D. Ph.

Baeteena Black

Executive Director



Lowry Drug Company's and AAHOMECARE SUMMARY OF COMMENTS

Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

At the very least, CMS should schedule a PAOC meeting after it publishes the standards. AAHomecare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

• Publication of the supplier standards

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

<u>Limitation on Beneficiary Liability</u>

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and

bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and "supplies used in conjunction with durable medical equipment;" enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CA for a product category?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Additional Criteria for Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

CMS should publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should also schedule a meeting of the PAOC to solicit

that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly
 different technologies. CMS should develop narrow product categories so that
 providers may submit proposals for more standard bases with general purpose
 seating and positioning products compared to high end complex rehab technology

not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance

services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

Bulletin at 1.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

The "inducement" element of the offense is met by any offer of valuable . . . goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.

Bulletin at 5 (Emphasis supplied).

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote *exactly* what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) – competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Please get a hold of this process before it is to late.

Sincerely,

Paul Lowry

VP Lowry Drug Company, Inc..

Top Rehab, Inc.

2110 N. Jackson St. Tullahoma, TN 37388



June 28, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Mark B. McClellan:

We are writing this letter in reference to the proposed rule for competitive acquisition of certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). We are physical therapists at Top Rehab in Tullahoma, Tennessee. Top Rehab is primarily an outpatient orthopedic clinic with physical, occupational, speech, and aquatic therapy. Top Rehab also offers industrial rehabilitation and health and fitness. In addition to outpatient orthopedics, Top Rehab offers treatment for ob/gyn, burns, wounds/ulcerations, vestibular disorders, sports and traumatic injuries, speech and swallowing disorders, and neurological conditions.

As therapists, we have a standard of care to provide the best care for our patients. Therapists tend to see patients on a regular basis which allows a therapist to make adjustments often. Therapists play an important role in providing equipment and supplies to patients to help with the patient's plan of care. The availability of products increase efficiency & timeliness for the patient. The patient can be fitted for an item before or after therapy.

Patients are often fitted for orthotics by therapists, and regular changes can be made as needed secondary to the therapist regularly seeing the patient. Fixing equipment becomes part of a therapist's job to encourage patient care, and this includes bending, trimming, molding, or assembling. There are many times a patient comes into the clinic after damaging or losing equipment that is needed immediately, and during these moments, a therapist offers the expertise of making the necessary adjustments. This is often convenient for the patient as well, and the patient feels comfortable with someone whom he has grown to trust.

Not only is this convenient for the patient, but the convenience is also for the therapist. Often the orthotics are needed to increase the patient's safety during activities. For example, a patient may need orthotics during walking to keep the patient's foot from rolling. Without the orthotic, a second individual may be required during therapy or the activity may not be possible.

We urge you to reconsider the proposed regulation and allow therapists to continue to supply orthotics to provide the best care possible to our patients. Thank you for your time and concerns.

Sincerely,

Angela Wehrle, PT

Lisa Hatfield, PT

Andrea Turner, PT

Rada Fults, PT

(252)

1330 Fragrant Spruce Ave Las Vegas NV 89123-5357 6/19/06

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am a physical therapist in Nevada. I teach at the University of Nevada, Las Vegas. Just prior to coming on board here at UNLV full time last fall, I did home care full time in Las Vegas and Boulder City, Nevada and did per diem work for the hospital in Boulder City, a nursing home in Boulder City, and a hospital here in Las Vegas.

I just learned from a colleague that your Agency is going to competitive bidding for some DMEPOS. I understand that physical therapists might be precluded from providing orthotics and some supplies to their patients as part of their plan of care.

During the course of my clinical work, I occasionally fit and provide assistive devices and orthotics for my patients. The patients I see are elderly and they are usually homebound or nursing home bound. As a result, it is very difficult and often very expensive for them to get to durable medical equipment providers and facilities providing orthotics. Being able to provide these items quickly and efficiently to my patients promotes safety in performing activities of daily living in their living situation and allows them to regain their mobility and return to self care more quickly. Most of these items require adjustments to fit each patient. Again, being able to do some molding of a wrist or hand orthosis for a patient with rheumatoid arthritis or a foot orthosis for a patient with plantar fasciitis in the home or nursing home can both assure a good fit (and thus function of the device) and save the patient or the facility a great deal of money in terms of patient transportation. In addition, over the course of time, I have learned which products work best for my older patients such as which spine orthoses for vertebral compression fractures due to osteoporosis. I can contact the physician and make recommendations as to those products which are easier for older clients to don and doff.

May I encourage your Agency to consider a revision of the proposed regulations so that physical therapists could continue to furnish orthotics in situations such as those described earlier? Thank you for your time and consideration of this request.

Sincerely.

Sue Schuerman, PT, GCS, PhD







7301 N. University Drive, Suite 305, Tamarac, Florida 33321 (954) 721-4806 (954) 721-9841 (FAX) Drwound@aol.com.

Robert J. Snyder, D.P.M., C.W.S.

Diplomat, American Board of Podiatric Surgery
Diplomat and Board of Directors, American Academy of Wound Management
Fellow, American College of Foot and Ankle Surgery
Fellow, College of Certified Wound Specialists
Member and Board of Directors, American Association of Wound Care
Medical Director, Wound Healing Center at University Hospital
Medical Director, Wound Healing Center at Northwest Medical Center

June 26, 2006

Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, Maryland 21244-8013

Re: Competitive Bidding and Negative Pressure Wound Therapy

To Whom It May Concern:

This correspondence will address my concerns regarding competitive bidding for, Negative Pressure Wound Therapy (NPWT), as well as the confusion "swirling about" relating to The VAC from KCI vs. the Versatile 1 from Blue Sky.

I am a Doctor of Podiatric Medicine (DPM) and a Certified Wound Specialist (CWS). I have been practicing for 31 years. My entire practice for the last 12 years has been strictly devoted to wound care, and I see hundreds of wounds per year. I have been using KCI's VAC Therapy (NPWT) for 3 years with extreme success. I believe in this therapy and have a concern that this will potentially be taken away from me and my patients as a result of the competitive bidding initiative. My concern stems from both my personal wound care experience and understanding the Competitive Bidding process as outlined on your website.

The following cases suggest the differences between two of the devices in the NPWT category:

1. A patient developed a large wound dehiscence status post Achilles tendon repair. After extensive debridement, VAC therapy NPWT from KCI was initiated while the patient remained hospitalized. After significant improvement was observed, that patient was discharged to a nursing facility and orders were written for continuation of VAC therapy from KCI. On a subsequent visit, however, it was noted that the wound failed to progress and in fact looked worse; further investigation uncovered that the nursing facility had substituted the Blue Sky Versatile 1 NPWT device for VAC NPWT. After

discharge, VAC therapy from KCI was re-instituted and the wound dramatically improved; treatment culminated with a split thickness skin graft and the ulcer completely healed.

2. A different patient presented to the wound care clinic with a cavernous lesion at the lateral aspect of his right leg. VAC therapy NPWT was ordered,; however, the nursing facility substituted the Blue Sky Versatile 1 NPWT. The Blue Sky device continues to sit idle in a plastic bag at the side of the patient's bed two weeks after delivery because no training was offered to personnel regarding application of the device.

It is my understanding that the proposed competitive bidding rules do not mandate the level of clinical studies, or clinical support for personnel, education/training programs, or service that would need to be provided with this and other therapeutic offerings. It is therefore likely that all non-essential services would be eliminated to reduce costs to the lowest possible threshold. This will surely lead to untrained personnel and inappropriate usage of NPWT specifically culminating in potential harm to my patients, longer lengths of stay (and increased costs), and ultimately, poor outcomes. KCI offers extensive support and educational endeavors representing the keys to successful therapy with the use of VAC. To the best of my knowledge, the Blue Sky DMEs do not!

Finally, and maybe most importantly, no significant research has been done utilizing the Blue Sky Versatile 1 device vs. VAC therapy from KCI whose extensive randomized controlled studies remain ongoing and publications continue to permeate the medical literature regarding the most appropriate uses of VAC therapy for healing complex wounds.

I respectfully request that Negative Pressure Wound Therapy be excluded from the competitive bidding process until more research can be undertaken and analyzed relating to the Blue Sky Versatile 1, or any other device using NPWT with gauze.

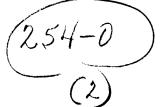
Thank you.

Sincerely,

Robert J. Snyder, DPM, CWS

Rehabilitation Medical Supply, Inc.

Bayamón Tel. 779-1681 Fax: 995-3761 Arecibo: Tel. 878-2915 Fax: 878-2917



Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
P.O. Box 8013
Baltimore, MD 21244-8013

June 23, 2006

Dear Sirs:

During 2003 and 2004 CMS allowed charges to Puerto Rico were higher than in the States due to the recognition of the added cost involved in importing DME Supplies, such as local importation taxes, shipment and transportation expenses, and freight insurance charges, but in year 2005 this Fee Schedule was reduced by CMS and presently the DME suppliers have to absorb this previous added costs, therefore the use of the Allowed Charges of 2004 to place us in the first 10 Metropolitan Statistics Areas for the Competitive bidding on 2007 is not correct.

Please consider this to fix the wrong calculated situation. Thanks you in advance for your consideration.

Cordially,

Jose I. Cruz

Delivery Technician

Rehabilitation Medical Supply, Inc.

Bayamón Tel. 779-1681 Fax: 995-3761 Arecibo: Tel. 878-2915 Fax: 878-2917



Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P P.O. Box 8013 Baltimore, MD 21244-8013

June 23, 2006

Dear Sirs:

The purpose of this letter is to express one of the reasons why we should not be considered or at least not in the first 10 Metropolitan Statistic Area in the Competitive Bidding Process.

During 2003 and 2004 CMS allowed charges to Puerto Rico were higher than in the States due to the recognition of the added costs involved in importing DME supplies, such as local importation taxes, shipment/transportation expenses and freight-insurance charges, but in 2005 this fee schedule was reduced by CMS and presently the DME suppliers now have to absorb these previous added cost, therefore the use of Allowed Charges of 2004 does not reflect the current reality of allowed charges in Puerto Rico, which the PAPC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

Cordially,

Sr. Luis D. Pabón Rodríguez

Manager



971 Maytum Avenue Sebastopol, CA 95472 June 27, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: "Proposed Rule for Competitive Acquisition of Certain DMEPOS".

I am writing to provide my comments regarding the <u>Proposed Rule for Competitive Acquisition of Certain DMEPOS</u>". I believe the proposed changes will have negative long term effects on rehabilitative health care for Medicare patients who are involved in a rehabilitation plan and under the care of a occupational therapist, physical therapist or speech therapist.

My Rehabilitation Credentials:

I have been an occupational therapist for 34 years and am licensed as an occupational therapist in California. I am a recognized expert in the field of hand rehabilitation. I have worked in a variety of settings, treating complex injuries of the hand including replants, crush injuries, tendon repairs, neurological and orthopedic conditions. I have established several successful clinics in Northern California including Vector Regional Hand Center, Eureka, ARMS (Associated Rehabilitation Medical Services) in Redwood City and SHARE (Spine Hand Arm Rehabilitation & Ergonomics) in Oakland. I have coordinated and presented at numerous continuing education courses for therapists, nurses, physicians in the area of hand rehabilitation, industrial rehabilitation and ergonomics.

Key Point:

As an occupational therapist, I urge CMS to revise the proposed regulations and establish a process that will enable rehabilitation therapists, i.e. occupational therapists, physical therapists, and speech therapists to continue to furnish orthotics, adaptive equipment for activities of daily living and home exercise equipment. These items are critical to the care of our patients and their ability to gain greater function enabling independence in their home environment. This rule could significantly impact the ability of therapists to furnish off-the shelf orthotics, wheelchairs, ambulatory assistive devices, and other items to their patients.

Although these products have been identified as products that require minimal adjustment and therefore have been included in the DME bid process, my 34 years experience as a therapist suggest that choices offered to a disabled seniors need criteria. These criteria

are generated through a thorough evaluation of the patient's physical limitations and the goals of their therapy program.

I urge CMS to allow physicians and therapists who have authorization to provide rehabilitation care to use all treatment procedures and supplies, orthotics and equipment necessary to facilitate independence in self care, ambulation, and promote safety in their home and community.

Patient Access to Rehabilitative Supplies and Equipment:

The allowable rehabilitation visits for Medicare patients are based on medical necessity, and a \$ 1740 financial cap, and therefore it is imperative that a therapist be involved at an early stage to effectively manage a patient's care.

Within these visit parameters, the therapist evaluates the patient's need for orthotics, ambulatory aids, self-care and ADL needs. A product that has been previously tested for its effectiveness is tried with a patient in the clinic setting. Sometimes, several over the counter orthotics need to be evaluated due to secondary complications such as skin condition, allergies, and peripheral neuropathies before a splint is chosen. Although there may be only a few adjustments to make, there is a great deal of patient education to know when to wear the splint, to identify pressure spots, and to recognize symptoms of inflammation.

Many of these rehabilitative products and aids are needed at the time of the initial evaluation. For example, a splint to support the wrist fracture or a cane/walker to begin ambulation. These devices are made available to the patient in the therapy setting to be taken home and used. No devices are issued without a clinical evaluation by the therapist and patient to determine efficacy for their specific diagnosis and rehabilitation plan. DME providers would not be able to determine which of many different products would benefit a specific patient.

In addition, mandating that these over the counter devices be provided outside of their rehabilitation provider will cause delays in their rehabilitation progress. Having to go elsewhere is burdensome to the patient and family member who must transport the patient somewhere else for the device. If the device does not meet the specifications that the physician and therapist feel are required of the over the counter product, such as a splint, much time has been wasted.

The idea of sending a away from the supervised rehabilitation provider to a DME provider without medical credentials to evaluate the need of a specific product will reduced the effectiveness of the patient's rehabilitation plan.

Therapists Routinely Make Adjustments to Orthotics:

Splints that are currently being proposed in the regulation are described as items that require "minimal self-adjustment." They define items requiring more than minimum self-adjustment as adjustments to items (e.g. bending, trimming, molding, or assembling) that must be made by a certified orthotist.

Occupational and Physical Therapists perform adjustments to both pre-fabricated splints and custom made splints as a routine part of their practice. Occupational therapists are trained in splinting in college and many states offer certification of occupational therapists as the clinician who evaluates and provides patients with orthotics.

The patient's response to a pre-fabricated splint, one size that does not fit all, may require inserts and management of the effects on skin. In addition, the Medicare population and their families need frequent and repetitive education to use the splints appropriately and to be able to recognize warning signs of misuse.

The Importance of Specific Brands:

Therapists and physicians collaborate to assess the patients and specify certain products that address the individual needs of patients. As an experienced occupational therapist, I urge CMS to revise the regulations to recognize the need for occupational therapists and physical therapists to be able to specify brands to prevent adverse medical outcomes. There is a difference in splints, self-care and ADL equipment, ambulatory equipment, and exercise equipment. The lease expensive could constitute an "adverse medical outcome".

Summary:

I am proud to identify myself as an occupational therapist specializing in hand and upper extremity injuries. I promote the practice of occupational therapy that means the therapeutic use of purposeful and meaningful goal-directed activities which engage the individual's body and mind in meaningful, organized, and self-directed actions that maximize independence, prevent or minimize disability, and maintain health. I know how necessary it is to my Medicare's patient's successful rehabilitation that their treating therapist be able to evaluate and provide prefabricated splints, custom made splints, home exercise items, ambulatory and sleeping aids, and activity of daily living products. To limit and obstruct the rehabilitation process will diminish the efficient use of therapy visits and be burdensome to our patients with limited mobility and function.

I again request CMS to revise the proposed regulations and establish a process that will enable occupational and physical therapists to continue to furnish orthotics, self-care and activity of daily living products, and home exercise equipment that are critical to the care of our Medicare patients.

Thank you for your attention.

Sincerely.

Linda J. Johnson, OTB/L. HTC

California Licensed Occupational Therapist

California Hand Therapy Certified



31 Dr. Veve Street Coamo, P.R. 00769 **Tel. 825-2929**



Plaza San Cristóbal Suite 216 - Second Floor Barranquitas, P.R. 00794 Tel. 857-4090

June 22,2006 Aibonito, Puerto Rico

Director

PO Box 2049

1 Vizcarrondo St.

Aibonito, P.R. 00705-2049

Tel. 735-8830

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

The language barrier that currently exists between Puerto Rico and the United States is an important factor that needs to be considered. Most of the people living in Puerto Rico are Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially,

Awilda Torres

Director



PO Box 2049 1 Vizcarrondo St. Aibonito, P.R. 00705-2049 **Tel. 735-8830**

31 Dr. Veve Street Coamo, P.R. 00769 **Tel. 825-2929** 254

Plaza San Cristóbal Suite 216 - Second Floor Barranquitas, P.R. 00794 **Tel. 857-4090**

June 22,2006 Aibonito. Puerto Rico

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

Please analize that if the event of tropical storms, hurricanes, sudden flooding and other occurrences, the nearest suppliers are the only ones that could provide the beneficiaries with very important equipment as oxygen tanks that are needed in regular basis. The implementation of the Compettive Bidding Program would cause that we, the small, community-based suppliers could be displaced by larger chain suppliers who are going to take advantage of economies of scale. This Program will make impossible to the beneficiaries who want to continue with Traditional Medicare and is going to create confussion about their rights to do so. They will loss the benefit of choose his supplier, the one that know him /she as a particular person and know his/her necessities, not a mere number in a record.

It is the freedom of selection that is currently provided by Traditional Medicare that must be carefully safeguarded.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially, Award Town

Awilda Torres

"Estamos muy cerca de usted"



234 Brenda Lane Columbiana, Ohio 44408

June 27, 2006

Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services Attention: CMS-1270-P PO Box 8013 Baltimore, MD 21244-8013

To Whom It May Concern:

I am a future pharmacist of this great nation writing in regards to recent CMS activities.

My first comment is in response to reimbursement cuts to community pharmacies. Decreasing reimbursement hurts the economic viability of pharmacies and ultimately results in the closure of businesses with subsequent pharmacist access limitations for all patients. It also reveals the sheer lack of appreciation that the government feels for pharmacists and the services we provide. The care that is afforded to each and every patient we serve is being publicly devalued when we are not adequately compensated. Instead of attacking the real problem, rampant fraud and abuse on the part of beneficiaries of these programs, you choose to punish the pharmacists who provide daily care to this population.

My second comment involves the recent DMEPOS proposal and my complete disapproval of it. It is not difficult to look back on both U.S. and world history to see that anywhere government regulations and rules take hold, the growth of the economy is stymied and businesses suffer. Free market competition is the only tried and true way to allow consumers/patients to benefit from the lowest prices possible whether it be related to health care products or otherwise. A completely free market succeeds 100% of the time. Government programs, particularly via CMS, have done enough damage to pharmacy already. Please let capitalism run its course. American businesses and consumers will be better off without your interference.

Sincerely,

Karli Gnipp

PharmD Candidate

Kaili - Ynipp, Pharms Candidate



June 30, 2006

259) Option Cave 8819 SS to Place West Mukiltee WA 98275

Honorable Mark B. McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

As Regional Director of Respiratory Services for Option Care Enterprises I am pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Option Care is a national infusion, specialty pharmacy, respiratory and home medical equipment services provider focused on meeting the needs of patients with acute and chronic conditions at home or in alternate site settings. We are a network of franchise and company owned locations and have been in operation since 1979. We have over 130 locations in 43 states and are growing. Option Care has recently been recognized by *Fortune* as one of the 100 fastest-growing companies and by *Crain's* as one of Chicago's fastest-growing public firms.

We acknowledge that CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. We also agree with AAHomecare, NHIA and AARC that prior to implementation there are issues that need to be addressed regarding national competitive bidding and some of which I have listed below:

1. Have Accreditation and Standards in Place before Starting
Only accredited providers should be eligible to submit bids. CMS should not
proceed with competitive bidding until it is sure that this is possible. CMS needs

to identify the criteria it will use to identify the accrediting bodies *now*. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

- 2. Getting It Right Is More Important than Rushing Implementation CMS should stagger the bidding in MSAs in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Also, the initial MSAs and products selected should be identified in the final rule. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.
- 3. Make Competitive Bidding Competitive, and Sustainable CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. It should not be implemented as restrictive competition.
- 4. Don't Make it Harder for Providers to Sell their Businesses
 The proposal to restrict the acquisition of a winning provider unless CMS needs
 to replace the supplier's capacity within the MSA places an inappropriate
 restriction on the provider's property rights. While it is appropriate for CMS to
 consider the buyer's quality and financial stability, CMS should not make
 approval of the acquisition contingent on the need to preserve capacity within the
 MSA.

5. Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 206-786-3508.

Sincerely,

Scott Alberts RRT

Regional Director Respiratory Services

Option Care Enterprises Inc.

(260)

Centers for Medicare/Medicaid Services

Attention: CMS-270-P

RE: Low Vision Aid Exclusion

Dear Sirs,	5/15/06
I am visually impaire	red and also
in very poor health. It	uso a CCTV.
magnifiers, very bright	
as very strong glasses.	
disability with not n	
coming my way.	
Please give us som	help with
our sieng aids. Put	
in our place. We put	you where
you are! Thank you.	
	ncerely,
	?K Coudr
•	

CARE PROVIDER SERVICES, INC.



June 29, 2006

Center for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in **opposition** to the proposed rule of Competitive Acquisition for Certain Durable Medical Equipment, Prosthetic, Orthotics and Supplies, CMS-1270-P. As a supplier to residents of skilled nursing facilities I have first hand knowledge of the problems created by this proposal. My company serviced skilled nursing facilities in Polk County Florida during the first testing stages of this program. The owners and operators of skilled nursing facilities were not notified of their inclusion or exclusion in the test until days before the deadline to start Phase One of the competitive bidding test. The skilled nursing facilities were finally notified that they would be excluded from the testing phase. As providers we were notified that we could continue to provide products to residents of the skilled nursing facilities but would be paid based on a separate fee schedule established by the competitive bidding process.

During the next twelve months of testing we continued to receive payments at the national fee schedule rates instead of the competitive bidding rates. Multiple calls were made to the DMERC carrier to discuss the overpayment situation with them. We were told at that time the payments were accurate. We were overwhelmed when two years later we received notices of recoupment for large sums of money stating we had been over paid for the twelve month period for all patients served in the Polk County Florida area.

The test of competitive bidding in a skilled nursing facility environment proved to be a failure during Phase One of the Polk County Florida test. After twelve months enteral feeding supplies were removed and the report published by the committee overseeing the test stated "enteral nutrition is not as-well suited for competitive bidding as other products". To propose once again after tests have proven it is not suitable for skilled nursing facilities does not show an educated decision making process.

There are substantial differences between home bound patients and those that required skilled nursing care. The skilled nursing facility patients are more clinically complex requiring greater care than patients in their homes. To pass a law that requires a skilled nursing facility to obtain services and supplies from a select group of vendors that they have no choice in choosing puts the resident's of the skilled nursing facilities health at risk. The skilled nursing facilities will also have to concern themselves with the legal ramifications created by these regulations. They are ultimately responsible for the health and well being of their residents. If the companies that are awarded the competitive bidding contracts fail to meet the quality of care for these residents, the skilled nursing facilities would be legally responsible.

By proceeding with this proposed rule you are putting the health and well being of the elderly residing in skilled nursing facilities at risk. As a supplier we strive to provide the highest quality of products and care to the residents we serve. Removing the freedom of choice that allows the skilled nursing facilities to choose the supplier that provides the highest level of care and service will create a law that cause poor quality of care for our elderly.

Respectfylly

Elizabeth Fago

William M. Hensley, PT, CI 300 Castlewood Court Johnson City, TN. 37601



June 27, 2006

Dr. Mark McClellan, MD, PhD
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS 1270P
P.O.Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

To start with, this looks like a long letter but if you will just read it through, you might see something you have not been told before.

I have been practicing Physical Therapy for fifty eight years and have seen a lot of changes, some changes good and some not so good. I finished School of Medicine in Physical Therapy at Duke and started practice in Johnson City in January 1950. There were less than 15 Physical Therapists in the state of Tennessee. Now we have four Physical Therapy schools in the state with several PT Assistant programs. There are now over 600 PTs in Tennessee. I a;so helpped establish the PT School at UT in Memphsis and the PT School at ETSU.

While working to improve programs and education in the state I have been in private practice in Johnson City, TN. I started and developed the PT Department at Johnson City Memorial Hospital, including the establishment of a polio center, keeping it functioning for four years through the epidemics. Worked with cripple children programs; started a prosthetic clinic covering four states; started many nursing homes and Home Health Agencies PT programs. I was the first in Tennessee to start home visits to patients who could not get into an outpatient clinic. So, I have had many years of experience in Physical Therapy.

Some of the bad things have shown up in greed. Doctors hiring Physical Therapist to work and perform therapy in their office, charging two or three times as much as a Private Practice Therapist can charge, using assistants at times. Limiting time for treatment of patients, therefore not doing a good full treatment of patients, limiting the possibility of a good outcome for the patient.

Home Health agencies that I helped start I found later that the owners were greedy and in order to make great profits insisted that the nurse, nursing aide, Physical Therapist, Occupational Therapist, Speech Therapist and some times the Social

worker visit the patient as soon and often as possible when the need was for only maybe two professionals to administer rehabilitation and bathing. There was a lot of waste in this type of operation.

With so many Home Health Agencies in the community, including new hospitals established, sending their own Home Health Care employees with the discharged patients, they manipulate the field by monopolizing health care. They over charge so that a private practice person who only does Physical Therapy, sees very few patients. The private practice Therapist can spend more time for rehabilitation of patients and relief of pain than one from an organization.

In my case of having my private office with many types of equipment for diagnosing and treating by the use of ultra sound and deep heat, I treat all types of patients. I was one of the first in the United States to use ultrasound in treatment of patients.

Medicaid in Tennessee would never pay me for seeing patients, but would pay hospitals in outpatient settings two or three times as much as I charged patients. I charged the small amounts so I could see them two to three times a week for faster follow ups, help prevent problems early and obtain better results.

Now Medicare has stopped paying for visits when patients have a chance to get a good recovery and keep functional.

I am at present seeing patients that have been discontinued by medicare, but I still see them and am supplementing the cost of keeping my office open with the use of my social security checks to help people.

Therefore it is time to do something about over charges in Home Health and Doctor's offices. Another thing, home health care will not see a patient in their home if a private physical therapist is giving them treatments. The private Physical Therapist must give up their patient to enable the patient to receive other needed care. In other words, the Home Health Care Agency wants to do all the care, not share. The same arrangement holds true in assistive living facilities. This is wrong, because the patients have the right to chose and not lose their total care.

Please consider the points that I have made in this letter.

Thank you for considering the above points,

William M. Hensley P.T. C.T. William M. Hensley, PT, CI

(Holder of License #I in the State of Tennessee)



31 Dr. Veve Street Coamo, P.R. 00769 **Tel. 825-2929**



Plaza San Cristóbal Suite 216 - Second Floor Barranquitas, P.R. 00794 **Tel. 857-4090**

June 22,2006 Aibonito, Puerto Rico

PO Box 2049

1 Vizcarrondo St.

Aibonito, P.R. 00705-2049

Tel. 735-8830

Center for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270P PO Box 8013 Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

The geographic location of Puerto Rico island, in the Caribbean Sea, should be bear in mind in the moment of the competitive bidding process. Yearlly our island is impacted by tropical storms and hurricanes. These cause so many problems to the roads, highways, and other access routes that many times interrupt the communication between towns. We, the small suppliers who are located in in different towns of the island are more accessible to the beneficiaries of that areas than the suppliers that are located in distant areas. The damage hurricanes, storms and floods cause to the island make impossible the accesibility of distant suppliers and the beneficiaries are acostumed to seek for the nearest one. The beneficiaries are acostumed to a long-standing relationship between them and we as their familiar suppliers. The large chain stores are not interested in the beneficiaries necessities as we do. We are always there for them, in bad and good times.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially,

Awilda Torres

Director

"Estamos muy cerca de usted"

Centers for Medicare/Medicaid Services Attention: CMS-270-P

RE: Low Vision Aid Exclusion

Dear Sirs,

This is in response to your proposal in
Section 414.15. It is not fair to people with low
vision to be excluded from medicine converge for how
Vision Aide and technologies. I have been aware
of the fact that wheelchairs, crutches, and bothwoom
aids have been approved by medicaris. Dowever,
I do not understand why medicare doesn't approve
Correge for Low Vision Aids such as magnifiers
and CCTV Systems. As you can see by the
difference in the two types of handwriting that
I am not able to see well enough to write
my oun letter. I am 86 years old and
On a fixed income. I, like many others)
meed this medicare coverage.
Dame Dumil

(265)

Centers for Medicare/Medicaid Services

Attention: CMS-270-P

RE: Low Vision Aid Exclusion

Dear Sirs. 6-13-06 my husbane has a magnic- Sight. What as blessing to have the low price air. now he can see printerer, de purples, read one s the signiture line on a check. I ortunately we were able to purchase the magne- Sight. I were though this war not cooker by medicare medicarie we felt this war a necessary purchase. Would have been worderful to have her some assistance. Instally there magnifien end be approved by there who have the centhrity to do so-

Mary Horgel 266 10 Neven a Centers for Medicare/Medicaid Services LODA 71 689 48 MARYHOUTZEL

Attention: CMS-270-P **RE: Low Vision Aid Exclusion** Dear Sirs, and but he go year see in blecomber I am hoping that medicin and Mit educate part decid to they the Many Pople That Commit afford to boy the pay the prin device that could have they All have to Pay and many can not afford.

there and could be helped . _ Palency maken in your derning Dates Ro No T 187 KISWA + OT

June 27, 2006

Centers for Medicare and Medicaid Department of Health & Human Services ATTENTION: CMS-1270-P P.O. Box 8013 Baltimore, Maryland 21244-8013

Re: Centers for Medicare & Medicaid Services (CMS)

42 CFR Parts 411, 414, and 424 (CMS –1270-P) RIN 0938-AN14

Medicare Program, Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and other Issues

To whom it may concern:

Thank you for the opportunity to offer comment on the proposed changes being contemplated for competitive bidding and acquisitions.

The concept of competitive bidding makes perfect sense, and as a taxpayer I want to provide the best service at the best price for our neighbors. However, the proposed manner in which the bidding is to occur will leave several dealers out of the picture, and as a result, our citizens will have limited choices and resources from which to depend for their home healthcare needs.

A better proposal would be to allow all accredited dealers to provide services at an assigned price. The price could be arrived at by bidding or by fee screens. But once assigned, all dealers should be able to provide the service and accept the assigned price. This would accomplish several major objectives- 1. raise the overall quality of services provided by having only accredited dealers participate. 2. lower the overall cost of services for the government and the beneficiary 3. provide for a larger number of dealers capable of providing services thereby enhancing beneficiary choices for services 4. maintain a system that can support product innovation and distribution for the beneficiaries 5. save millions of dollars in cost for CMS for not having to implement the competitive bid process and roll it out over several years.

As for the acquisition proposals, I am okay with all of the proposals, except I am really troubled by the oxygen ownership proposal. I have over 20 years experience providing home oxygen and respiratory services, and am a Registered Respiratory Therapist. The ownership of the oxygen equipment could put undue stress on beneficiaries. What happens when problems arise with the equipment? Who do they call? Do they seek emergency treatment at a hospital? Do they go to an Urgent Care Center? Who can handle their issues without adding cost to the healthcare systems in which they live?

A better proposal would be to cap-rent the equipment at 36 months, but have the dealer retain ownership. CMS would no longer pay a rental fee, but perhaps could

pay a lower service fee once every three months to offset the cost of maintaining the equipment and portability. This would be an assigned agreement so the beneficiary would be protected. This too would accomplish several major objectives. 1. lower the overall cost to CMS and the beneficiary. 2. provide for a larger overall network of providers to service the beneficiaries. 3. removes the burden of maintenance and servicing of the oxygen equipment from the beneficiary and has it remain with the dealer 4. provides for continued service coverage 24/7/365 for the beneficiaries 5. provides for stability within the system for the beneficiaries and dealers 6. maintains traditional responsibilities for the dealers and beneficiaries.

Thank you for considering my inputs and comments.

Respectfully.

Daniel J. Mach

Manager

Munson Home Medical Equipment

3816 West Front Street

Traverse City, Michigan 49684

HOSKINS DRUG STORE NO. 2 111 N. MAIN STREET CLINTON, TENNESSEE 37716	(8) M@DOO LETTER
PH: 423-457-4340 FAX: (865) 463-0678	Date 6-27-06
To CMS	Subject
	COMPETITIVE BIDDING PROGRAM
MY SISTER AND I OWN to	•
> EST, IN 1930 BY OUR FATHER	
3 DME IN MID 1960 INTO A	
CONTINUED DO OFFER SERVICES	
POPNY ? CAMPBILL COUNTIES TO	
BEEN DEDICATION DI COMMUNITS	W/ QUALITY SERVICE. PLEASE
ALLIW US TO CONTINUE IN	YEARS TO COME. WE ARE A
FULL SSEVICE PRARMACY DM	E WITH TRAINED STAFF.
ENCLOSED YOU WILL FIND OUT	
STATEMENT.	
•	PATIENT W/ MI THEIR DME NCEDS
	\cup



Tennessee Pharmacists Association

TPA RESOLUTION 99.1

To Honor Rolland Carvel (Dudley) Hoskins

WHEREAS, R. C. (Dudley) Hoskins was the oldest living registered pharmacist in Tennessee and one of the oldest in the United States, and an outstanding leader in the pharmacy profession; and,

WHEREAS, he distinguished himself and his profession in active practice for nearly three-quarters of a century; and,

WHEREAS, he served on the Tennessee Board of Pharmacy from 1963 to 1968, and as President of the Tennessee Board of Pharmacy in 1967; and,

WHEREAS, Dr. Hoskins served many years in leadership positions with distinction and honor, on the Clinton Board of Education, the Clinton Civitan Club, the Clinton Housing Authority, and as the first President of the Clinton Chamber of Commerce; and

WHEREAS, he graduated from the University of Tennessee College of Pharmacy in 1926, and was named a lifetime member of the University of Tennessee College of Pharmacy Alumni Association Board of Directors; and

WHEREAS, he was co-founder of the Center for Pharmacy Management and Research at the UT College of Pharmacy and endowed the Katherine and Dudley Hoskins Scholarship Fund; and,

WHEREAS, Dudley Hoskins was name Tennessee Pharmacists Association's Pharmacist of the Year in 1984; and,

WHEREAS, Dr. Hoskins' life profoundly enriched his community, his state, and his profession,

THEREFORE, BE ITRESOLVED that the Tennessee Pharmacists Association recognize and memorialize the life of this dedicated pharmacist.

BE IT FURTHER RESOLVED that a copy of this resolution be properly prepared and presented to the family of R, C. (Dudley) Hoskins.

Submitted by Senator Randy McNally, D.Ph Representative Shelby Rhinehart, D.Ph.

Adopted on proper motion by the Tennessee Pharmacists Association House of Delegates February 9, 1999, Nashville, Tennessee

MISSION STATEMENT

Our Mission as a Family owned and operated business is to provide quality care and exceptional service that is second to none. Everyday may we strive to provide family friendly service and always go above and beyond to ensure the satisfaction of each and every customer.

Pharmacist and healthcare providers are at and near the top of the list of most trusted professionals. Protecting a patient's health information is essential to maintaining a patient's trust and keeping the providers reputation. At Hoskins Drug Store we pride ourselves in our sincerity and ability to help patients while maintaining a strong sense of confidentiality.

Under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, Hoskins Drug Store protects the civil rights of all patients. Benefits will not be denied, nor do we discriminate on the grounds of race, color, national origin or handicap.

If we do not have an item in-stock, or if we are unable to help a patient, it is our policy to refer the patient to an entity that can fulfill their needs.

Medical Supply

City-on City-on City-on City-on

Ve carry

Visit Silve

...to brandages
And commission
Stockers
We have a sult

933 Market St . Chinon





2600 S. Raney Effingham Illinois 62401

Phone: (217) 342-3412 (USA Only) (800) 879-0117

Fax: (217) 342-3384 www.jointactivesystems.com

June 30, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

We are Joint Active Systems, Inc. (JAS). We are an Illinois corporation and currently employ about 70 workers. In addition, more than 160 individuals in other States work for JAS throughout the country. We manufacture clinically-proven, patented, static progressive stretch devices/orthosis used to treat restricted range of motion in the shoulder, elbow, wrist, forearm pronation/supination, knee, ankle, and finger joints secondary to trauma, surgery, immobilization, burns, or neurologic injury. More importantly, we have enrolled in the Medicare Program for the sole purpose of supplying and billing only the devices that we manufacture. JAS requested and obtained the following Healthcare Common Procedure Coding System (HCPCS) codes for its devices: E1801, E1806, E1811, E1816, E1818, and E1841. We respectfully submit our comments to the proposed rule regarding the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), which was released on May 1, 2006 (71 Fed. Reg. 25654).

1. General Comments

We strongly urge the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the competitive acquisition program (CAP) for DMEPOS items until the Supplier Quality Standards (Quality Standards) are finalized and released by CMS. CMS must not require suppliers to make a competitive bid on any DMEPOS item without affording them the opportunity to be informed about the additional cost that they must incur in order to comply with the new Quality Standards. The benefits of true competition as Congress intended can only be realized if the suppliers have all of the facts that are necessary to make informed bids.

As you know, even the Program Advisory and Oversight Committee (PAOC) recommended that CMS delay the CAP until the Quality Standards are made available to the suppliers, especially given that, according to CMS, significant revisions have been made to the draft Quality Standards that were introduced on September 26, 2005. Furthermore, CMS has stated that it would release the final version of the Quality Standards in June of 2006. To date, CMS has not done so. Therefore, JAS requests that CMS accept the recommendation of the PAOC.

2. Criteria for Item Selection

If an entity that is the sole manufacturer and supplier of a particular DMEPOS item is unable to bid or participate in CAP, then the Medicare Program has effectively eliminated access to this DMEPOS item by the beneficiaries. This clearly is not the intent of Congress. Therefore, CMS must exempt such manufacturer-suppliers from the proposed requirement that all suppliers bid for all items in a particular product category to be finalized and announced by CMS. Instead, in order to protect each beneficiary's access to such single-source DMEPOS items, manufacturers like JAS that supply only those DMEPOS items that they manufacture should be afforded the same exemption proposed for skilled nursing facilities (SNFs) and physicians. Like SNFs and physicians providing DMEPOS items only to their patients, manufacturer-suppliers are not "commercial suppliers" because they do not supply every DMEPOS item reimbursable by the Medicare Program.

Alternatively, CMS should phase in such single-source DMEPOS items and manufacturer-suppliers after 2009. Delaying the inclusion of such items and suppliers will allow CMS to not only learn about the effects of CAP in general but also address the unique issues of single-source DMEPOS items and manufacturer-suppliers in particular. Likewise, CMS must designate the product categories narrowly. CMS must permit suppliers to bid for those DMEPOS items that only they can supply. By requiring suppliers to bid for every DMEPOS item in a product category, CMS would hinder true competition and fail to assure the most savings because the one manufacturer-supplier that could provide the lowest bid would actually not be able to bid because it only supplies those DMEPOS items that it manufactures.

In addition, CMS must comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and actually "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must seriously consider excluding from CAP those DMEPOS items that are supplied only by the manufacturer. Congress did not intend CAP to prevent Medicare beneficiaries from accessing DMEPOS items that CMS has coded and has been reimbursing prior to either the enactment of the Medicare Modernization Act of 2003, which mandated the CAP, or the implementation of CAP itself.

3. Submission of Bids under the Competitive Bidding Program

CMS must only apply CAP to "commercial suppliers." Just as CMS realized that SNFs and physicians are not "commercial suppliers," CMS must understand and acknowledge that manufacturers that only supply the DMEPOS items that they manufacturer are not "commercial suppliers." While SNFs and physicians supply the full range of DMEPOS items only to their

patients, manufacturer-suppliers supply only those DMEPOS items that they manufacture. Therefore, because of the limited type of DMEPOS items that such manufacturer-suppliers provide to Medicare beneficiaries, they are less of "commercial suppliers" than even the SNFs and physicians supplying every type and quantity of DMEPOS items.

Again, CMS must designate the product categories narrowly. CMS simply must permit suppliers to bid for those DMEPOS items that only they can supply. It is not only logical but also beneficial to the Medicare beneficiaries. For JAS, it would be particularly ironic if it could not bid or participate in CAP. In 2005, JAS met with CMS (Joel Kaiser and a few DME Regional Carrier medical directors) to discuss the pricing of the codes for its devices that JAS has requested and obtained through the HCPCS coding process. CMS has not yet responded to the request to increase the reimbursement rates. Now, JAS is struggling with the painful requirement that all bids must be lower than the current Medicare rates. It would indeed be a slap in the face if CMS were to deny JAS, the sole supplier of the devices that it manufacturers, the opportunity to even bid because CMS defined the product categories broadly. Most importantly, the Medicare beneficiaries would be denied access to these clinically effective and cost efficient devices, which require 3 months of wear-time on average and not the 15 (now 13) months permitted by CMS.

4. Conditions for Awarding Contracts

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

5. Opportunity for Participation by Small Suppliers

CMS must consider the small manufacturers like JAS that have enrolled in the Medicare program only to be able to supply the DMEPOS items that they manufacture. These manufacturers have accepted this course, despite the risk of being subject to various additional Medicare restrictions (e.g., Stark self-referral prohibitions), because they have experienced problems merely selling their DMEPOS items to Medicare "commercial suppliers." They want to ensure that their DMEPOS items are properly delivered to, fitted by, and used by the Medicare beneficiaries. CMS must not penalize such manufacturer-suppliers.

Section 1847(b)(6)(D) addresses the "protection" of small suppliers and not just the identification of such suppliers. Therefore, CMS must treat small suppliers differently. Manufacturers that only supply the DMEPOS items that they manufacture are not "commercial suppliers" that supply the full and complete list of DMEPOS items. CMS must actively help small suppliers, including manufacturer-suppliers, so that they may participate in CAP and provide the Medicare beneficiaries access to such single-source DMEPOS items.

6. Opportunity for Networks

CMS must provide sufficient time for suppliers to establish and work collaborative in the networks permitted by CMS under the proposed rule if CMS truly wishes to allow suppliers to form networks in order to bid competitively. CMS must not erroneously believe that the potential fo

volume is the motivating factor for the suppliers. Instead, CMS must realize and accept the fact that suppliers want to and need to bid and participate in CAP to merely stay in the Medicare program.

7. Quality Standards and Accreditation

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

On behalf of over 230 hard-working families of JAS, we thank you for the opportunity to comment on the proposed CAP for DMEPOS items. We hope that CMS will truly consider each of our comments.

Sincerely,

Dean Kremer

President

cc: Sandra Bastinelli (via e-mail)

Carol Blackford (via e-mail)

Dan Mr

Stacy Coggeshall (via e-mail)

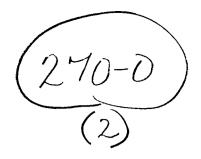
Joel Kaiser (via e-mail)

Martha Kuespert (via e-mail)

Herb Kuhn (via e-mail)

Walt Rutemueller (via e-mail)

Linda Smith (via e-mail)







Tuesday, June 20, 2006

To:

Mark B. McClellan, MD, PhD

From:

Joyce Westfall

Occupational Therapist Westlake Hospital 1225 W. Lake Street Melrose Park, IL 60160

Subject:

NOT in support of the current draft language re: qualified providers & accreditation standards for orthotics. NOT in support of competitive bidding for prefabricated

orthoses.

In compliance with the Medicare Modernization Act of 2003, I understand that the Secretary of Health and Human Services is responsible for establishing a competitive bidding system and quality standards for certain durable medical equipment, prosthetics and orthotics (DMEPOS). Furthermore, I understand the quality standards, which include the professionals recognized as qualified suppliers are being developed for approval by your Program Advisory Oversight Committee.

As a therapist, I have great concern for the language regarding who is qualified to provide orthoses to beneficiaries. The current draft language specifically indicates orthotics and prosthetics "require the qualifications and expertise of a certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". This language does not include occupational therapists and physical therapists. The language does not correspond with the existing language outlined in the Social Security Act, Section 1834(a)(20).

I cannot understand why CMS would consider restricting providers to orthotists and prosthetists and mandate accreditation standards through the O & P boards. The omission of therapists does not correspond with current CMS regulations. TODAY, occupational therapists and physical therapists are recognized as qualified CMS providers for evaluating patients, designing, fabricating, and dispensing the appropriate orthosis, along with educating the patient (e.g. applying/removing the orthosis, understanding the wearing schedule and precautions). Occupational therapists and physical therapists are specifically identified as qualified practioners in the Social Security Act, Section 1834(a)(20), and our status as a practitioner also qualifies us as suppliers for these devices. TODAY, there are thousands of therapists throughout the country fabricating customized orthoses and issuing prefabricated orthoses to patients. We are highly trained and highly qualified professionals who have a long-standing history of fabricating orthoses in this country.

It is important to know the minimal educational standards for occupational therapists and physical therapists are either a bachelor or master's degree. Orthotics is included in our academic curriculum. Both occupational therapists and physical therapists must successfully pass national boards at the completion of the academic experience before applying for licensure or certification at a state level. These examinations are administered through national testing companies accredited by NOCA and ANSI, which

are recognized by CMS today. This academic background is complemented with clinical experience and ongoing medical education. We serve as authors for peer-review journals, manuals and books on orthoses, and have lectured to our profession and others on the subject. In addition, beyond our high academic standards, many therapists choose to have additional certifications, one example being the certified hand therapist (CHT). CHTs have a minimum of five years of practice experience and have successfully passed an examination specific to the upper quarter (shoulder, elbow, wrist and hand). Specific questions related to orthotics are included in the examination. Once certified, recertification is mandated each five years to retain the CHT designation. This is accomplished through medical education requirements and practice involvement (i.e. clinical practice, research or education) related to the upper extremity. The Hand Therapy Certification Commission (HTCC), is responsible for the administration process for becoming a certified hand therapist and subsequently recertifying. Their website can be accessed at www.htcc.org.

We are sought out by patients, businesses, industry, case managers, referring physicians and therapists to treat patients with special medical problems. There are lofty expectations and demands placed on us to provide the highest level of patient care and remedy their medical condition. Often, we are the last opportunity to improve the patient's medical condition and quality of life. The physicians and therapists communicate closely about the patients and their medical condition or surgery. As therapists, we have a strong working knowledge of the medical conditions/surgeries and anatomy of the affected area. With this expertise we can carefully craft the proper rehabilitation program and determine the necessary orthosis. I cannot begin to imagine that my patients would receive an initial evaluation and treatment by the physician/surgeon, subsequently be referred to therapy for a portion of the therapy services and then go to another facility to receive the orthosis or orthoses they need. Evaluating the patient, fabricating and dispensing the orthosis, determining the wearing schedule and educating the patient about their orthosis is an integral part of hand therapy. Often it is the orthosis that is key to a successful outcome! It is those frequent, little adjustments that can result in terrific functional outcomes!

It is equally important to understand that sending patients to another provider fragments and disrupts the continuity of patient care. It is difficult enough for our Medicare and Medicaid patients to drive to office visits and therapy, let alone requiring them to drive to another location for additional services. During the course of therapy most of the patients require a number of adjustments to their orthoses, which would result in multiple trips to the DME distributor. These adjustments are necessary due to frequent dressing changes, fluctuation in edema, progression of the treatment plan, and patient progress. I can only imagine the burden and confusion this would cause for the patient and family.

With respect to competitive bidding for prefabricated orthoses, how could therapy providers possibly participate in the competitive bidding process? We are at a huge disadvantage. Therapists are not in the business of manufacturing and supplying high volumes of medical equipment. Individually, each therapist and/or therapy facility dispenses small volumes of medical supplies to their patients. There is no way therapists could compete with respect to wholesale pricing, volume warehousing, and having the business infrastructure for wide-scale distribution within their medical model today. The small amount of profit generated from these prefabricated orthoses serves, at best, as a very small source of revenue.

I must believe there has been an accidental oversight on behalf of the committee as the quality standards and accreditation process for orthotics and prosthetics has evolved. It is strongly recommended the language state: "orthotics and prosthetics require the qualifications and expertise of a licensed, certified or registered occupational therapist, physical therapist OR certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". In addition, I do not believe there can be a genuine interest in the small volume suppliers (i.e. therapists) participating in competitive bidding. Therapists should be exempt from the competitive bidding process.

It is so important for the committee to understand how instrumental occupational therapists and physical therapists are in providing both custom-made and prefabricated orthoses to patients, your beneficiaries. Respectfully, I ask that you give this letter full consideration and act on these major concerns.

Jegee Westfall OTR/L, CHT







Tuesday, June 20, 2006

To:

Mark B. McClellan, MD, PhD

From:

Crystal Guyton

Occupational Therapist Westlake Hospital 1225 W. Lake Street Melrose Park, IL 60160

Subject:

NOT in support of the current draft language re: qualified providers & accreditation standards for orthotics. NOT in support of competitive bidding for prefabricated orthoses.

In compliance with the Medicare Modernization Act of 2003, I understand that the Secretary of Health and Human Services is responsible for establishing a competitive bidding system and quality standards for certain durable medical equipment, prosthetics and orthotics (DMEPOS). Furthermore, I understand the quality standards, which include the professionals recognized as qualified suppliers are being developed for approval by your Program Advisory Oversight Committee.

As a therapist, I have great concern for the language regarding who is qualified to provide orthoses to beneficiaries. The current draft language specifically indicates orthotics and prosthetics "require the qualifications and expertise of a certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". This language does not include occupational therapists and physical therapists. The language does not correspond with the existing language outlined in the Social Security Act, Section 1834(a)(20).

I cannot understand why CMS would consider restricting providers to orthotists and prosthetists and mandate accreditation standards through the O & P boards. The omission of therapists does not correspond with current CMS regulations. TODAY, occupational therapists and physical therapists are recognized as qualified CMS providers for evaluating patients, designing, fabricating, and dispensing the appropriate orthosis, along with educating the patient (e.g. applying/removing the orthosis, understanding the wearing schedule and precautions). Occupational therapists and physical therapists are specifically identified as qualified practioners in the Social Security Act, Section 1834(a)(20), and our status as a practitioner also qualifies us as suppliers for these devices. TODAY, there are thousands of therapists throughout the country fabricating customized orthoses and issuing prefabricated orthoses to patients. We are highly trained and highly qualified professionals who have a long-standing history of fabricating orthoses in this country.

It is important to know the minimal educational standards for occupational therapists and physical therapists are either a bachelor or master's degree. Orthotics is included in our academic curriculum. Both occupational therapists and physical therapists must successfully pass national boards at the completion of the academic experience before applying for licensure or certification at a state level. These examinations are administered through national testing companies accredited by NOCA and ANSI, which

are recognized by CMS today. This academic background is complemented with clinical experience and ongoing medical education. We serve as authors for peer-review journals, manuals and books on orthoses, and have lectured to our profession and others on the subject. In addition, beyond our high academic standards, many therapists choose to have additional certifications, one example being the certified hand therapist (CHT). CHTs have a minimum of five years of practice experience and have successfully passed an examination specific to the upper quarter (shoulder, elbow, wrist and hand). Specific questions related to orthotics are included in the examination. Once certified, recertification is mandated each five years to retain the CHT designation. This is accomplished through medical education requirements and practice involvement (i.e. clinical practice, research or education) related to the upper extremity. The Hand Therapy Certification Commission (HTCC), is responsible for the administration process for becoming a certified hand therapist and subsequently recertifying. Their website can be accessed at www.htcc.org.

We are sought out by patients, businesses, industry, case managers, referring physicians and therapists to treat patients with special medical problems. There are lofty expectations and demands placed on us to provide the highest level of patient care and remedy their medical condition. Often, we are the last opportunity to improve the patient's medical condition and quality of life. The physicians and therapists communicate closely about the patients and their medical condition or surgery. As therapists, we have a strong working knowledge of the medical conditions/surgeries and anatomy of the affected area. With this expertise we can carefully craft the proper rehabilitation program and determine the necessary orthosis. I cannot begin to imagine that my patients would receive an initial evaluation and treatment by the physician/surgeon, subsequently be referred to therapy for a portion of the therapy services and then go to another facility to receive the orthosis or orthoses they need. Evaluating the patient, fabricating and dispensing the orthosis, determining the wearing schedule and educating the patient about their orthosis is an integral part of hand therapy. Often it is the orthosis that is key to a successful outcome! It is those frequent, little adjustments that can result in terrific functional outcomes!

It is equally important to understand that sending patients to another provider fragments and disrupts the continuity of patient care. It is difficult enough for our Medicare and Medicaid patients to drive to office visits and therapy, let alone requiring them to drive to another location for additional services. During the course of therapy most of the patients require a number of adjustments to their orthoses, which would result in multiple trips to the DME distributor. These adjustments are necessary due to frequent dressing changes, fluctuation in edema, progression of the treatment plan, and patient progress. I can only imagine the burden and confusion this would cause for the patient and family.

With respect to competitive bidding for prefabricated orthoses, how could therapy providers possibly participate in the competitive bidding process? We are at a huge disadvantage. Therapists are not in the business of manufacturing and supplying high volumes of medical equipment. Individually, each therapist and/or therapy facility dispenses small volumes of medical supplies to their patients. There is no way therapists could compete with respect to wholesale pricing, volume warehousing, and having the business infrastructure for wide-scale distribution within their medical model today. The small amount of profit generated from these prefabricated orthoses serves, at best, as a very small source of revenue.

I must believe there has been an accidental oversight on behalf of the committee as the quality standards and accreditation process for orthotics and prosthetics has evolved. It is strongly recommended the language state: "orthotics and prosthetics require the qualifications and expertise of *a licensed, certified or registered occupational therapist, physical therapist OR* certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". In addition, I do not believe there can be a genuine interest in the small volume suppliers (i.e. therapists) participating in competitive bidding. *Therapists should be exempt from the competitive bidding process*.

It is so important for the committee to understand how instrumental occupational therapists and physical therapists are in providing both custom-made and prefabricated orthoses to patients, your beneficiaries. Respectfully, I ask that you give this letter full consideration and act on these major concerns.

Sincerely.

Cuplet Guyto Orly



RGAN 12 ATLONS LISTED ON LAST

Goldberg, Ralph (CMS/CMM)

From:

Blackford, Carol W. (CMS/CMM)

Sent:

Friday, June 30, 2006 2:09 PM

To:

Ballantine, Lorrie T. (CMS/OCSQ); Keane, Michael P. (CMS/CMM); Rutemueller, Walter E.

(CMS/CMM); Kaiser, Joel E. (CMS/CMM); Goldberg, Ralph (CMS/CMM); Jacobs, Karen N.

(CMS/CMM); Meholic, Alexis (CMS/CMM); Smith, Linda D. (CMS/CMM)

Cc:

Kuespert, Martha D. (CMS/CMM)

Subject:

FW: Comments on DMEPOS Competitive Acquisition Proposed Rule - Sign-on Letter

Attachments: Written Comments2 DME comeptitive bidding 63006 - final.pdf

FYI

Carol Blackford (410)786-5909 carol.blackford@cms.hhs.gov

From: Mari Johnson [mailto:Mari.Johnson@ama-assn.org]

Sent: Friday, June 30, 2006 12:07 PM

To: Blackford, Carol W. (CMS/CMM); Kaiser, Joel E. (CMS/CMM); Bromberg, Barry J. (CMS/OFM); Bossenmeyer,

James M. (CMS/OFM); Brandt, Kimberly L. (CMS/OFM); Zone, Lisa C. (CMS/OFM)

Cc: Margaret Garikes: Katie Tenoever: Sharon McIlrath: Dawn Robinson

Subject: Comments on DMEPOS Competitive Acquisition Proposed Rule - Sign-on Letter

Attached, please find comments in the form of a sign-on letter on the Proposed Rule on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654 (May 1, 2006).

Please feel free to contact me if you have any questions.

Mari

Mari Rose Johnson, MPA Assistant Director, Federal Affairs American Medical Association 1101 Vermont Avenue, NW Washington, DC 20005 202-789-7414 (o) 202-294-3828 (c) 202-789-4581 (f) Mari.Johnson@ama-assn.org

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Administrator McClellan:

The undersigned organizations appreciate the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654 (May 1, 2006).

Under the DMEPOS proposed rule, CMS would implement a competitive bidding program for certain Medicare-covered items of DMEPOS. We have several important concerns about the proposed rule, which we raise to protect our patients from any unintended harmful effects of the new initiative.

EXEMPTION FOR PHYSICIANS AND NON-PHYSICIAN HEALTH CARE PRACTITIONERS FROM DMEPOS COMPETITIVE BIDDING PROGRAM

In accordance with the mandate under the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) to implement a DMEPOS competitive bidding program, CMS is proposing that physicians who supply DMEPOS must submit bids and be awarded contracts in order to furnish the items included in the competitive bidding program.

We urge CMS to exempt from the DMEPOS competitive bidding program physicians and certain other health professionals, e.g, podiatrists, optometrists, physical and occupational therapists, physician assistants (collectively referred to hereinafter as "practitioners"), who provide their own patients with DMEPOS. Instead, when these practitioners are licensed by their state board to practice in that state, they could be "deemed" as qualified to provide patients with DMEPOS, and current payment policy would apply to these practitioners for these items of DMEPOS.

Practitioners generally operate as small businesses (and small suppliers of DMEPOS), and the financial and administrative burden of complying with the new competitive bidding program, simply to supply DMEPOS to their own patients, likely will be too great. Yet, practitioners must be integrally involved in providing DMEPOS to their patients to ensure that (i) a particular item of DMEPOS meets the "size and fit"

specifications for that particular patient; and (ii) the patient is properly instructed concerning the use of that DMEPOS. This is necessary to provide patients with the highest quality of care, achieve patient compliance, reduce risk of further injury and avert liability concerns as well.

For example, if a patient is diagnosed with a foot fracture, a walking boot and crutches may be required upon leaving the physician's office. If the patient is unable to acquire the item from the treating physician and must obtain the item from another supplier due to the new competitive bidding program, serious adverse consequences could result, including a delay in care, continuous or exacerbated pain, or the patient could be at risk for additional, increased injury, which would increase costs to the Medicare program. This could also result in fragmented care, which could disrupt the patient-practitioner relationship. Moreover, in some cases, Medicare allows only one item of DMEPOS per patient. In this event, if the item is not initially properly fitted and sized, the patient may later have to pay out-of-pocket for a replacement item.

Further, the clinical judgment and expertise of the treating practitioner in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect or the patient receives insufficient information about an item, the patient will likely return to the practitioner's office with questions or for assistance. This will result in increased costs to the Medicare program and will increase utilization under the sustainable growth rate (SGR). Thus, practitioners should be exempt from the DMEPOS competitive bidding program for the purpose of providing their own patients with DMEPOS.

In the alternative, if CMS does not provide this exemption, CMS, at the very least, should phase these practitioners into the bidding process after 2009. In accordance with the MMA DMEPOS mandate, CMS will phase-in this program with respect to certain Metropolitan Statistical Areas (MSAs) in 2007 and 2009, with additional competitive bidding occurring in other areas after 2009. A phase-in for certain areas, with an additional phase-in after 2009 for practitioners who provide their patients with DMEPOS would also conform to the spirit of the MMA mandate, which contains a provision to protect small suppliers of DMEPOS.

As discussed above, practitioners operate as small businesses and the cost of complying with the competitive bidding program and related requirements could effectively prohibit them from supplying patients with DMEPOS that is most appropriate when supplied at the time of the patient visit. Thus, these practitioners should have lead time before applying the competitive bidding program to them. If patients do not have access to enough suppliers who offer the needed product categories, this could seriously impact access to appropriate care. Finally, this phase-in time will allow practitioners time to identify those DMEPOS items that should not be part of the competitive bidding program, as further discussed below.

If practitioners are phased-in over time, however, CMS should provide a less burdensome process for practitioners, including an exemption from the accreditation standards that may be appropriate for a large regional or national DMEPOS supplier, but are much too burdensome for practitioners who merely provides DMEPOS to their patients.

EXEMPTION FOR CERTAIN ITEMS FROM THE DMEPOS COMPETITIVE BIDDING PROCESS

Under the proposed rule, as discussed above, physicians that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items included in the competitive bidding program for the area in which they provide medical services. The rule also states that physicians must ensure that any arrangement under which they refer for and furnish DMEPOS under a competitive bidding program must be in compliance with the physician self-referral law.

We understand that certain DMEPOS arrangements may be prohibited by the physician self-referral law. While we are not advocating for a repeal of this provision of the self-referral law, we, nevertheless, note that there is an exemption from the law for certain items of DME. Some items, such as canes, crutches, walkers and folding manual wheelchairs, were exempted because the patient requires the item to depart from the physician's office. In addition, there is a separate exemption from the physician self-referral law for implants furnished by an ambulatory surgery center (ASC), including, but not limited to, cochlear implants, intraocular lenses and other implanted prosthetics, implanted prosthetics devices and implanted DME that meet certain requirements. Certain other services and prosthetic devices, such as eye glasses or contact lenses following cataract surgery, were exempted to avoid significant inconvenience to Medicare patients and because they are already subject to frequency and payment limits.

Similar to this physician self-referral law, we urge CMS to apply current payment policy to and exempt from the competitive bidding program the above-listed and other similar items (including, but not limited to, wrist, ankle and finger splints; shoulder, elbow and hand splints; aircasts; cervical collars; orthotic inserts; spine stabilization braces; corsets; and rib belts) that practitioners provide to their patients. It is our understanding that prosthetics devices are not among the items covered in the MMA's competitive bidding provision. However, we note that even if prosthetics were covered under the law, there should be an exemption for physicians providing these devices to their patients. This will ensure quality of care and patient safety. We also urge CMS to work closely with the undersigned organizations to develop an appropriate list of exempted DMEPOS to ensure patient care is not impeded. To maintain transparency and equity in this process, CMS should provide an opportunity for review and public comment with regard to this list.

ELIGIBILITY TO PARTICIPATE IN THE DMEPOS COMPETITIVE BIDDING PROGRAM

The proposed rule states that "providers that furnish Part B items and are located in a competitively bidding area and are also DMEPOS suppliers" must submit bids in order to

furnish competitively bid items to Medicare beneficiaries (emphasis added). The proposed rule does not define the term "provider." In the event that CMS does exempt practitioners from the DMEPOS competitive bidding program as requested above, we urge CMS to clarify that certain health care professionals who are not MDs or DOs and who regularly provide their patients with DMEPOS would be considered "providers" for purposes of participating in the DMEPOS bidding process and could be awarded a contract as a DMEPOS supplier. Some of these practitioners may provide their patients with Medicare DMEPOS, and thus should be permitted to participate in the competitive bidding process.

QUALITY STANDARDS AND ACCREDITATION FOR SUPPLIERS OF DMEPOS

The proposed rule provides that DMEPOS suppliers will be required to meet applicable quality standards specified by the Secretary of the Department of Health and Human Services. Although quality standards are set forth under existing law, the Program Advisory and Oversight Committee (PAOC) was mandated by the MMA to advise the Secretary with respect to certain functions, including (i) the implementation of the Medicare DMEPOS competitive bidding program; and (ii) the establishment of quality standards for DMEPOS suppliers. In fact, the PAOC has already held meetings concerning the development of new quality standards for suppliers. In addition, draft proposed quality standards are posted on the CMS web-site.

We have strong concerns about implementing a regulation that requires suppliers to meet quality standards that are in transition and have yet to be finalized. Public comments can only focus on existing quality standards, yet, we understand that new standards will be applied on top of the existing standards. This creates confusion and does not provide physicians and other impacted parties an opportunity for meaningful review and comment, as required by the Administrative Procedures Act. We urge CMS to clarify the quality standards that suppliers must meet under the DMEPOS competitive bidding program, and if new quality standards are developed, CMS should issue a formal proposed rulemaking before moving forward with the DMEPOS competitive bidding program to ensure proper notice and opportunity to comment on any new quality standards.

OPPORTUNITY FOR NETWORKS

CMS proposes that suppliers may form networks for DMEPOS bidding purposes. Such networks would be comprised of several companies joined together through a legal contractual relationship to submit bids for a product category under competitive bidding. CMS notes in the proposed rule that although no networks submitted bids for the demonstration project, it may be a useful option for suppliers in some cases.

We believe that this option would be very unrealistic for physicians who supply patients with DMEPOS. It would require: (i) expensive legal resources to set up the network while guarding against anti-competitive and other antitrust concerns, as well as (ii)

additional, significant administrative resources. Thus, it is unlikely that physicians would be able to take advantage of this option.

PHYSICIAN AUTHORIZATION/TREATING PRACTITIONER

The MMA mandate for the DMEPOS competitive bidding program allows the Secretary to establish a process by which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual. CMS is proposing that the physician or treating practitioner would be able to determine that a particular item would avoid an adverse medical outcome, and that the physician or treating practitioner would have the discretion to specify a particular product brand or mode of delivery. The proposed rule further states that when a physician or other treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the competitive bidding area (CBA) that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary.

We agree with CMS that the physician or treating practitioner should have the sole discretion to make these kinds of determinations about the individual medical needs of their patients and that suppliers should be required to furnish the particular item requested by the physician or treating practitioner.

The proposed rule further states that if, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare as this would be considered a non-covered item.

We urge CMS to aggressively monitor contract suppliers to ensure that they do not: (i) unilaterally provide a different item than that specified in the physician's or treating practitioner's written prescription, thereby depriving patients of access to the most appropriate care, as determined by their physician or treating practitioner; and (ii) burden physicians with unnecessary or repeated requests to revise their orders, thus delaying necessary care for a patient and leaving a patient at risk of further injury.

REBATE PROGRAM

CMS is proposing to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid amount and the single payment amount.

Although we appreciate that beneficiaries have the opportunity to benefit from system-wide savings, the rebate program, as structured, is unfair to physicians. This would allow some physicians, who win a supplier contract award, to provide patients with a rebate, while other physicians, who do not win a contract, may be unable to provide their patients with a particular item of DMEPOS. The inherent inequity in this system underscores the need to exempt physicians who provide their own patients with DMEPOS from the competitive bidding program.

OFF-THE-SHELF ORTHOTICS

Items subject to the DMEPOS competitive bidding program would include, among others, off-the-shelf orthotics (OTS). CMS sets forth a proposed definition of OTS in the rule and states that the agency will consult with a variety of individuals, including experts in orthotics, to determine which items and/or HCPCS codes would be classified as OTS orthotics. We encourage CMS to include medical organizations that represent physicians who provide off-the-shelf and custom-made orthotics in that consultation process, and we look forward to further clarification of this issue.

MONITOR IMPACT OF DMEPOS COMPETITIVE BIDDING PROGRAM

We urge CMS to aggressively monitor the impact of the DMEPOS competitive bidding program on patient access to care. This is an entirely new and complex program that will significantly change the market dynamics for supplying DMEPOS to patients, and CMS must ensure that these market changes do not unintentionally limit the current variety of DMEPOS available to patients, thereby adversely impacting patient access to these important Medicare items.

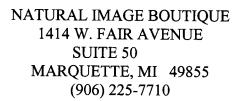
In addition, CMS should ensure that patients have adequate choice of suppliers within their locality, in addition to any mail order options. Patients (especially when injured) or their caretaker should not have to travel long distances to obtain needed DMEPOS as this could put patients at risk and increase Medicare costs. Thus, we urge CMS to ensure that suppliers are available across competitive bidding areas, and not concentrated in one or a few areas of a locale.

We appreciate the opportunity to comment on this new Medicare competitive bidding program for DMEPOS, and look forward to working with CMS to address the critical issues raised above.

Sincerely,

American Academy of Nurse Practitioners
American Academy of Ophthalmology
American Academy of Physician Assistants
American Academy of Sleep Medicine
American Association of Orthopaedic Surgeons

American College of Osteopathic Surgeons American College of Surgeons American Gastroenterological Association American Medical Association American Occupational Therapy Association American Optometric Association American Osteopathic Academy of Orthopedics American Physical Therapy Association American Podiatric Medical Association American Society of Cataract and Refractive Surgery American Society of Hand Therapists American Society of Plastic Surgeons American Urological Association Child Neurology Society Medical Group Management Association National Association of Spine Specialists





June 26, 2006

Mark B. McClellan, M.D., PhD Administrator Centers for Medicare & Medicaid Dept. of Health & Human Services 7500 Security Blvd. Baltimore, MD 21244

Attention: CMS-1270-P

Dear Mr. McClellan:

As a Certified Pedorthist who has been in practice for 10 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would implement a new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition to being a Certified Pedorthist, I am also an ABC Certified Fitter of Orthotics and a Fitter of Breast Prosthetics and Bras.

Presently, I am experiencing difficulty with the Medicare Plus Blue program in Michigan which allows Blue Cross Blue Shield of Michigan to oversee this federally funded Medicare program. I am located in the Upper Peninsula and BCBS awarded all DMEPOS supplies to Wright & Filippis, excluding all other DME providers. Wright & Filippis, as I have recently been informed, is on the Board of Directors for BCBS of Michigan and ABP, the facilitator for this program, is a subsidiary of Wright & Filippis as stated on their reimbursement checks.

I visit outlying clinics as well, which are in excess of 50 miles from the closest Wright & Filippis office, but ABP will not make an exception even for these areas. Since I am out-of-network, even though I've been seeing many of these patients for 5 to 10 years, they are no longer able to see me unless they pay 50% out-of-pocket. Now, this just doesn't seem to make a lot of sense to me.

The economy being such that it is, seems to be putting many small businesses out-ofbusiness. I recently had to close my store and am now employed by a podiatrist. However, I have to reapply for a new DMERC number for my breast and orthotics fitter claims since this is not covered under the scope of practice for a podiatrist. I do understand this and I am in the process of doing the same. However, I feel that in order to cut insurance costs, you will be causing many companies to either go bankrupt or quit business and allow a large conglomerate to monopolize the DME industry. I do feel this should be investigated and re-evaluated. I accept assignment from DME and BCBS so I guess I don't see how any money is being saved. Plus, many of my patients, especially women who have had mastectomies, do not feel they get a proper fit and many of them claim that they are not even being measured. They do not want to go to Wright & Filippis, but they have no other choice.

I hope you will not allow this situation to continue. Many businesses are being hurt by this and one large corporation is being allowed to grow even larger.

Thank you for your anticipated cooperation in this very important matter.

Sincerely,

Sharon L. Tabor, CPed/CFo

. Meron T. Talion





2730 Ambassador Caffery Parkway P. O. Box 61160 Lafayette, LA 70596-1160 337.988.1585 1.800.582.2435 www.cardio.com

June 26, 2006

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To Whom It May Concern:

The process of competitive bidding by CMS that may effect how I, as a physician, am able to deliver healthcare has come to my attention. As a cardiothoracic and vascular surgeon with over 20 years of clinical experience, I have relied heavily on the wound VAC from KCI in San Antonio, TX for almost all of my surgical wound complications and even more so recently in our work to heal wounds and save limbs in the treatment of critical limb ischemia (CLI) where > 80% of all amputations are preceded by an open wound or ulcer. The clinical and economics of CLI and amputations are greatly misunderstood and underappreciated. I will enclose some recent work we have done on this subject. There are an estimated 220,000 – 240,000 amputations yearly in the US and Europe and the estimated costs of CLI yearly are between \$10-20 billion US dollars. Unfortunately we are limited in the number of effective clinical tools to treat the CLI and especially the wound complications after complex surgical procedures.

I am concerned that the CMS competitive bidding may result in an inability to recommend the highly effective VAC therapy in my patients despite the fact that there is mounting clinical evidence in its safety and efficacy in treating this patient population. VAC therapy has been scientifically proven to heal wounds and save legs and has extensive worldwide positive results. I know of no other as effective treatment for my patients and improved outcomes always translate into saved dollars and cost effectiveness.

I have knowledge of the Blue Sky Versatile 1 medical product that has claims to delivering negative pressure wound therapy but I am not aware of any scientific data regarding its merits. I do not believe this is an equivalent therapy to the VAC and if forced to use this therapy versus VAC therapy, I am concerned that

the patient outcomes will be negatively impacted. Simply stated, I do not think the Blue Sky technology is nor any other similar product is as safe and effective as the well-proven VAC therapy.

It is my strong suggestion that CMS strongly consider delaying the competitive bid process in this clinical area until more information can be accumulated comparing similar therapies. New therapies come and go but only therapies that have appropriate scientific data and a long-term positive track record should be involved in any competitive bidding when clinical outcomes, lives and limbs of our patients are at stake. I am concerned about the lack of data with the Blue Sky product and I am keenly aware of my results with the wound VAC and their proven results. I respect the work of the CMS and respectfully make these comments and suggestions.

Sincerely, all Edde

David E Allie, MD

Director of Cardiothoracic and Endovascular Surgery

Cardiovascular Institute of the South/Lafayette

DEA/kt

Enclosures

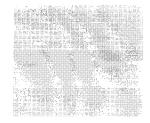
Critical Limb Ischemia: A Global Epidemic A Critical Analysis of Current Treatment Unmasks the Clinical and Economic Costs of CLI

David E. Allie, MD; Chris J. Hebert, RT, R-CIS; Mitchell D. Lirtzman, MD; Charles H. Wyatt, MD; V. Antoine Keller, MD; Mohamed H. Khan, MD; Muhammad A. Khan, MD; Peter S. Fail, MD; Krishnamoorthy Vivekananthan, MD; Elena V. Mitran, MD; Sonja E. Allie, MBA; Gary Chaisson, RT, R-CIS; Samuel J. Stagg, III, MD; Adam A. Allie, MS; Michael W. McElderry, MD; Craig M. Walker, MD

KEYWORDS Critical Limb Ischemia, Current Treatment, Primary Amputations, Interventional Revascularization, Costs

Abstracts

Background: Multiple reports document the higher costs of primary amputation (PA) compared to infrainguinal bypass surgery (IBS). Recent reports document 40-50% cost-effectiveness for percutaneous transluminal angioplasty (PTA) compared to IBS. The literature suggests appropriate initial treatment for critical limb ischemia (CLI) to be IBS = 38%, PTA = 28%, and PA = 16%. The encouraging 6-month Laser Angioplasty for Critical Limb Ischemia (LACI) 93% limb salvage rate prompted an independent CLI and LACI clinical and economic analysis. Methods: Between 1999-2001 a reference amputation population (RAP) of 417 patients with at least one infrainguinal amputation were identified from a 2.5 million patients Medicare/insurance dataset. Clinical data and all medical cost claims for 18 continuous months, 12-month prior and 6-month post-amputation, were analyzed for PTA, IBS, and PA treatment pathways. Based on multiple assumptions and the LACI phase II results, economic outcomes were used for a LACI pathway analysis compared to PTA, IBS and PA pathways by substituting the LACI trial pathway as the initial treatment in lieu of the RAP actual treatment. Results: Initial treatments for CLI RAP were PA = 67%, IBS = 23%, PTA = 10%; A majority of wound complications (80%) and myocardial infarction 7/9 (77.7%), stroke 13/16 (81.2%), and death 2/2 (100%) occurred in the PA RAP. Only 35% of the RAP had an ankle brachial index (ABI) and only 16% angiography before PA. 227/417 (56%) of the RAP had multiple procedures. Average total costs / patient = \$31,638 without LACI and \$25,373 with LACI. Average savings/patient with LACI = \$6,265. Conclusion: The most common current treatments in the US for CLI are still characterized by high rates of primary amputations, multiple procedures, and high rates of procedure-related complications. Despite the limitations and assumptions of this analysis, the utilization of a LACI pathway first revascularization treatment strategy may provide clinical and economic cost savings in treating patients with CLI.



Corresponding to: David E Allie, MD - Chief of Cardiothoracic & Endovascular Surgery - Cardiovascular Institute of the South/Lafayette 2730 Ambassador Caffery Parkway - Lafayette, LA 70506 (800) 582-2435 -toll free - (337) 988-1585 -main line

Introduction

Critical limb ischemia (CLI) remains incompletely characterized in the clinical literature. Therefore information, knowledge, and awareness surrounding the clinical impact of CLI remains obscure. There exists an even greater paucity of data and less understanding regarding the clinical costs of treating CLI and amputation to the patient, family, and to society. It is estimated that between 220,000 - 240,000 major and minor lower extremity amputations are performed in the United States (US) and Europe yearly for CLI¹⁻⁵. In the US the amputation rate has increased from 19 to 30 per 100,000 persons years over the last two decades primarily due to an increase in diabetes and advancing age⁶⁻⁷. Despite advances in cardiovascular treatment, in patients over 85 year of age an amputation rate of 140 per 100,000 persons/year has been reported with a primary amputation (PA) still carrying an excessively high mortality rate of 13-17%⁷⁻⁹. In the highest risk patients, 30-day periprocedural mortality after amputation can range from 4 - 30% and morbidity from 20 - 37%¹⁰, because many end-stage CLI patients will suffer from sepsis and progressive renal insufficiency. Successful rehabilitation in patients after below knee amputation is achieved in less than twothirds and in less than one half after above knee amputations and overall, less than 50% of all patients requiring an amputation ever achieve full mobility11-14.

CLI: The Natural History

Wolfe *et al.* classically described the natural history of CLI in a collation of 20 publications on 6118 patients by stratifying them into a low-risk cohort of 4089 patients (rest pain only and ankle pressure > 40mmHg) and a high-risk cohort of 2029 patients (rest pain and tissue loss with or without ankle pressure < 40mmHg) 15 . At 1 year, 95% of the high-risk group and 73% of the low-risk group required a major amputation without revascularization. A 75% limb salvage rate was achieved at 1 year in the high-risk group with revascularization. The cumulative probability of survival for the entire group was 74% at 1 year, 58% at 2 years, 56% at 3 years, 48% at 4 years, and 44% at 5 years. Multiple reports have repeatedly documented the poor overall prognosis for the CLI patient with mortality rates greater than 50% after three years $^{16-17}$. Within one year of the diagnosis of CLI, 25% will require a major amputation and another 25% will be dead $^{5.18}$.

Interestingly, recent reports by Panayiotopoulos *et al.* and Kalra *et al.* have shown significantly improved long-term survival after revascularization and limb salvage as compared to CLI patients following revascularization failure and amputation^{6,19}. Statistically significant five-year survival rates were achieved after limb salvage in the Kalra *et al.* report⁶. Clearly the clinical costs to the CLI patient are extremely high underscoring the need for a characterization of the clinical and economic costs involved in treating CLI especially considering the incidence of CLI is expected to significantly increase yearly approaching global epidemic proportions.

CLI: The Data?

Inherent problems in obtaining pertinent economic outcome information in CLI include a lack of standardization of reporting, defini-

tions, hospital and payer charges and costs, changing technology and the lack of a consensus CLI treatment pathway between clinicians and institutes in both the US and Europe⁵. CLI is often treated differently by each medical specialty and treatments can vary between geographical locations. Several European CLI economic reports appeared in the late 1980's and early 1990's and were included in the cost analysis of the TransAtlantic Inter-Society Concensus (TASC) document reported in January, 200016. This document though did not include any of the new technologies and strategies used today in a more "modern" revascularization approach to treating CLI, limb salvage, and Primary Amputation (PA). Unfortunately, since 2000, few data have reported the clinical and economic costs of CLI further demonstrating a need for information. Furthermore, divergent reports exists in the literature regarding the economic treatment costs of infrainguinal bypass surgery (IBS) and PA with sparse data available reporting the costs of percutaneous revascularization procedures for treating CLI including percutaneous transfermoral angioplasty (PTA) or excimer laser revascularization

The purpose of this analysis was to determine the clinical characteristics of treating CLI in a more "modern" US patient population and to determine the potential to improve clinical and economic care with the use of excimer laser revascularization (Laser Angioplasty for Critical Ischemia or LACI) in the treatment of CLI. To this end, we investigated standard-of-care clinical treatment pathways of patients with CLI; examined population characteristics and actual treatment patterns of a reference population of 417 CLI patients who ultimately experienced amputations; and estimated the expected clinical impact on their care if a LACI first pathway had been used in lieu of the first PTA, IBS, or PA. During this study, we examined 18 months of medical claims prior to each patients qualifying amputation from a 2.5 million patient Medicare and insurance dataset, and identified incidence and costs associated with three clinical treatment pathways, including PTA, IBS, or PA. The LACI assumptions were based on the Laser Angioplasty for Critical Limb Ischemia (LACI) Phase II clinical outcomes.

Methods

Study Population

Between 1999-2001, a Reference Amputation Population (RAP) of 417 patients with at least one infrainguinal amputation was identified from a data source of 2.5 million patients in a large Medicare and commercial insurance dataset. Clinical data elements evaluated included all patient records covering inpatient hospital care, in patient rehabilitation, skilled nursing services, hospital patient care (including ambulatory surgery), physician data, pharmacy claims and other outpatient services including podiatry and home health. The data review and analysis was conducted by Strategic Health Resources®, an independent consulting and data-mining firm, and commissioned by The Spectranetics Corporation. To qualify as part of the RAP patients had to meet all of the following criteria:

A. A lower amputation of any kind during the final six months of the 18-month study period. The final amputation during this period became the "qualifying amputation" for the purpose of establishing

the study period. This resulted in a data evaluation for 18 continuous months on each RAP, 12-month period prior and 6-month post amputation.

- **B.** Continuous insurance eligibility for 18 months prior to the date of the qualifying amputation.
- **C.** Documented CLI based on having at least one qualifying diagnosis or specified combination or diagnosis and procedure codes in the patients record prior to or concurrently with the amputation.

To be included in the RAP at least one of the following diagnostic criteria had to be documented:

- **A.** Documentation of lower extremity atherosclerosis with rest pain or ischemic ulceration or gangrene; or,
- **B.** Documentation of gangrene alone, only if it occurred in conjunction with hospital records specifying amputation associated with peripheral vascular disease (PVD), or,
- **C.** Documentation of diabetes with manifestation of PVD, if and only if it was present as the principle diagnosis for the qualifying amputation.

To avoid inadvertent inclusion of patients whose amputations could relate to non-CLI etiologies, specific exclusions included:

- A. All patients with a cancer diagnosis.
- B. Any "accident or injury" codes.
- C. All patients with a paraplegia or quadriplegia code.

Utilizing these criteria, a RAP of 417 CLI patients was obtained with an average age of 70.9 years. The RAP was 59% male and overwhelmingly 82% diabetic.

CLI Treatment Pathways Categories

To characterize the process of care, we defined treatment care pathways identifying common sequences of key procedures and grouped them according to the first index key procedure recommended for CLI treatment including PA, IBS, and PTA. We identified common sequences of subsequent key procedures and grouped them into nine treatment care pathways (Table 1).

Based on our comparisons of recommended treatment of CLI to the

Table 1. Treatment Care Pathways.

Pathway Group	Pathway Description	# Patients	% Total Population
Amputation	Single primary amputation	190	46%
First	Multiple primary amputations	67	16%
	Primary amputation + additional revascularization procedures	24	6%
Bypass First	Primary bypass followed by single amputation	56	13%
ado	Primary bypass + revisions and litional revascularization procedure	18 es	4%
	Primary bypass followed by multiple amputations	22	5%
PTA First	Primary PTA followed by single amputation	17	4%
	Primary PTA + additional revascularization procedures	7	2%
	Primary PTA followed by multiple	16	4%
	amputations	417	100%

clinical pathways identified in the study, it appears that PA was used to a much greater extent than the clinical literature suggests, while PTA and IBS procedures appear underutilized. Specifically, 67% of patients in our study population had a PA as their first index treatment, while the literature suggests this approach would be best for approximately 16% of CLI patients²⁰⁻²³. In contrast, 23% of patients had an IBS as their first CLI treatment, while the clinical literature suggests this approach for an estimated 38%²⁰⁻²³. Likewise, in the RAP, 10% of CLI patients had a PTA first treatment, while the clinical literature recommends this approach for an estimated 28%²⁰⁻²³.

Claims Analysis

For each of the 417 CLI patients in the RAP, all claims for 18 continuous months *prior* to the qualifying amputation were evaluated. For patients with multiple amputations, all claims for 18 months prior to the first qualifying amputation occurring during the final six months of the study period, continuously through the last qualifying amputation were included. All claims related to procedures for the treatment of CLI were evaluated and divided into the following categories:

- *Diagnostics and Evaluation* PVD assessment and patient evaluation for treatment prior to or concurrent with the first key procedure identified by best practice clinical algorithms taken from literature review
- Pre-op care Visits coded as pre-op exams prior to a key procedure.
- Revascularization procedures/amputations Any amputation, IBS, or PTA ("Key Procedures").
- **Key Procedure Episode** Services provided during the outpatient or inpatient stay (including rehabilitation) for any key procedure, excluding dialysis-related care.
- **Post-Procedure care** Defined as routine post-procedure care (relevant physician visits, home health, revisions, and appropriate services) to amputated stumps, verified through discussions with clinicians.
- **Procedure-related complications** Defined as all complications occurring within closely defined time periods following a relevant key procedure, or infections. Complication definitions were taken from the literature analysis and verified through discussions with clinicians.
- **Pharmaceutical use** Defined as CLI-related medications taken during the study period.

Results

Clinical Data Analysis

Procedure-related complications were a frequent occurrence in the RAP. Overall 290 complications were identified with 80% associated with an amputation. Wound infections and stump dehiscence were the most frequent complications and myocardial infarction, stroke and death were associated with amputations (Table 2). Multiple amputations and revascularization were also frequent in the RAP (Table 3).

An analysis of the CLI patient noninvasive and invasive diagnostic pre-procedural work-up prior to a PA was performed. Shockingly, less than one half (49%) of the RAP had **any** diagnostic vascular

Table 2. Number of Complications Associated with each Type of Key Procedure.

(4) (4) (4) (4) (4) (4) (4) (4) (4) (4)		190	Key Procedure Group			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Complication Category	Amputation	Bypass Graft	Combo with Amp	PTA	PTA-Bypass Graft	Grand Total
Wound Infection	47	4	1	2		54
Complication with stump	53					53
Major Infection - Sepsis	32	3	3			38
Major Infection - UTI	20	1	1			22
Early Graft Occlusion/Malfunction	9	4	2	2	1	18
Major Infection - Pneumonia	14	3				17
Deep Vein Thrombosis	11	2		3		16
Stroke	13	2		1		16
Procedure-Related Bleeding/ Wound Healing	9			2		11
Myocardial Infarction	7	1	1			9
Renal Failure	4	1	3			8
Leg Edema	4	1		1		6
Myointimal hyperplastic lesions	3	2	1			6
Other Complication	4	1				5
Graft Infection		2	1			3
Hematoma Puncture Site		2	1			3
Aortaenteric fistula		2				2
Death	2					2
False Aneurysm			1			1
Grand Total	232	31	15	11	1	290

Table 3. Average Revascularizations and Amputations per Patient by Pathway.

		Average Number	r of Procedi	ıres per Patient		
Pathway	PTA	Bypass	Amp	PTA-Bypass Graft	Combo including Amp[1]	Grand Total
Single primary amputation			1.0			1.0
Multiple primary amputations			2.3			2.3
Primary amputation + additional revascularization procedures	0.2	0.6	2.4	0.042	0.4	3.6
Primary bypass followed by single amputation		0.8	0.8		0.2	1.8
Primary bypass followed by multiple amputations		0.9	2.0		0.1	3.0
Primary bypass + revisions and additional revascularization procedures	0.1	1.9	1.5		0.3	3.9
Primary PTA followed by single amputation	0.9		0.9		0.1	1.9
Primary PTA followed by multiple amputations	0.9		2.1		0.1	3.1
Primary PTA + additional revascularization procedures	1.2	0.7	1.1	0.063	0.1	3.1
Grand Total	0.1	0.3	1.4	0.005	0.1	1.9

^[1] A procedure is included in the "Combo" column if two or more procedures were performed on the same day, or if they were performed during the same admission and data to separate them was insufficient.

evaluation prior to a PA with the incidence of ABI, angiography and MRA being 35%, 16%, and 1% respectively (Table 4-5).

Clinical Practice Analysis

An evaluation of the physician and medical service providers / specialties seen by the RAP during and between episodes of CLI treatment was obtained (Table 6). The percentage of radiology, cardiol-

ogy, and vascular surgery services provided were 39%, 26%, and 21% respectively.

LACI Clinical Outcomes

The Laser Angioplasty for Critical Limb Ischemia (LACI) trial was a prospective registry to evaluate limb salvage rates in poor or non-surgical candidates (patients who were likely to receive an amputa-

Table 4. Vascular Assessment Prior to First Key Procedure.

First Key Procedure	# Patients with Vascular Assessment	Total # Patients in Pathway Group	Percent of Patients Receiving Vascular Assessment Before First Key Procedure
Amputation	138	281	49%
Bypass	67	96	70%
PTA	33	40	83%
Total	238	417	57%

Patients are considered to have had vascular assessment if a qualifying ICD-9 procedure code or CPT Code appears anywhere in the patient's claims records during the study period on or before the date of the first Amputation, Bypass Graft, or PTA.

tion) who underwent excimer laser assisted revascularization. The LACI phase II trial enrolled 145 patients with 155 critically ischemic limbs (rest pain and/or ischemic ulceration with established tissue loss) with 423 lesions treated with excimer laser at 15 US and German sites²⁵. Periprocedural results included no deaths or acute limb ischemia and a 96% laser/PTA success rate with 90% receiving "straight-line follow" to the foot. Results at 6 months included only a 2% requirement for IBS, 16% overall secondary reintervention rate, and 93% limb salvage rate. The LACI phase II study demonstrated that laser assisted endovascular intervention in this fragile CLI population results in excellent limb salvage rates with low complication and secondary intervention rates without adding excessive clinical risks.

CLI Treatment Pathways with LACI

As mentioned above, all patients treated in the LACI II trial were poor surgical candidates who would have required PA if revascularization was not performed. As such, the LACI patient population may resemble this RAP series. These 417 patients were analyzed to impute the potential outcomes if the LACI procedure were performed. Potential outcomes of the LACI procedure were defined in three pathways: LACI with total limb retention; LACI with a reintervention; and LACI, with or without a reintervention, followed by an

Table 6. Mix of Medical Service Providers/Specialties Rendering Care.

Provider Category	# Patients	% Patients Having a Visit [1]	Average # Visits
Home Health Care	162	53%	20
Internal Medicine	120	39%	9
Radiology	118	39%	6
DME/Prosthetics/Supplies	100	33%	4
Independent Lab	96	31%	5
Other	95	31%	3
Nephrology	87	29%	21
Cardiology and Cardiovascular Disease	78	26%	7
General Surgery	72	24%	5
Laboratory	70	23%	5
Family/General Practice	65	21%	5
Emergency Medicine	64	21%	2
Cardiovascular/Thoracic/			
Vascular Surgery	63	21%	3
Ambulance/Transportation	63	21%	5
Pathology	58	19%	5
Podiatry	58	19%	4
Anesthesiology	54	18%	3
ER	49	16%	2
Surgery	43	14%	2
Orthopedics/Orthopedic			
Surgery	33	11%	4
Infectious Diseases	33	11%	8

[1] Percentages are based on the 305 patients (of 417 in study population) who had provider visits during and after the first episode of care for a PTA, Bypass Graft, or Amputation.

Table 5. Vascular Assessment Prior to First Key Procedure: Detail.

Pathway Group	Assessment Type	# Patients [1]	# Patients with Vascular Assessment	% of Assessed with Type of Assessment	Total # Patients	% of Total
Amputation First	ABI	98	138	71%	281	35%
Amputation First	Angiography	45	138	33%	281	16%
Amputation First	MRA	3	138	2%	281	1%
Amputation First	Other	74	138	54%	281	26%
Bypass First	ABI	48	67	72%	96	50%
Bypass First	Angiography	42	67	63%	96	44%
Bypass First	MRA	1	67	1%	96	1%
Bypass First	Other	44	67	66%	96	46%
PTA First	ABI	25	33	76%	40	63%
PTA First	Angiography	16	33	48%	40	40%
PTA First	MRA	1	33	3%	40	3%
PTA First	Other	19	33	58%	40	48%

amputation. Based on LACI Phase II results, we allocated the LACI patients into the three pathways as follows:

- LACI with total limb retention (62%)
- LACI + downstream reintervention (13%)
- LACI +/- downstream reintervention + amputation (25%)

Thus, the 65% of patients converting to LACI are expected to have the following distribution:

- 40% LACI with total limb retention
- 9% LACI + downstream reintervention
- 16% LACI +/- downstream reintervention + amputation

Accordingly, we estimate the average CLI patient costs treated with LACI in lieu of the first PTA, IBS or PA for the three LACI pathways. The cost for LACI with total limb retention was developed from the following components:

- The cost of "simple" PTA (with serious adverse events and a length of stay of four days or less);
- Additional physician and outpatient facility reimbursement under standard Medicare policy for use of the laser (we assume that commercial insurers will adopt the same differential on average);
- Normal follow-up care (for a simple PTA);
- An allowance for treatment costs of SAE in patients who did not experience post-hospital reintervention or amputation. (Post-hospital reintervention or amputation moves the patient to a different pathway):
- An allowance for treatment costs of subsequent lesions, which we identified in 6.5% of our study population. (Use of LACI in one lesion is assumed to have no impact on the development of disease in another lesion).

Economic Data Analysis

The total average cost of each of the nine CLI treatment pathways was calculated beginning with the first key procedure and included all services, complications, procedures and related costs.

Applying the LACI assumptions and calculations, we estimated the average CLI patient treated with LACI in lieu of first PTS, IBS, or PA would generate \$20,487 in medical costs for CLI-related proce-

dures and costs over a period of six months during and after the LACI treatment. A detailed breakdown of costs by pathway was calculated for the LACI first group as compared to the standard therapies evaluated in the RAP group (Tables 7 and 8).

Across the entire RAP, the average costs per patient for CLI-related treatment was \$31,638. Extrapolating the data from the LACI trial and applying it to 65% of the RAP group, it is estimated that use of LACI would result in an average cost per CLI patient of \$20,487 therefore generating a savings of \$6,265 per patient across the entire CLI population (Table 9).

Discussion

Clinical CLI data on the treatment of CLI suggest that almost all patients should undergo a vascular assessment and a high percent of CLI patients should be recommended revascularization to avoid amputation. Despite this noble ideal, an analysis of actual reimbursement claims data suggests that a significant majority of patients in the U.S. are still "treated" with primary amputation (PA). The clinical and economic costs of PA as a standard therapy are high, when compared to revascularization and limb salvage²⁶⁻²⁹. In 1978, Stoney *et al.* proposed a PA as the best cost-effective solution to treating CLI²⁶. However, it has never been demonstrated scientifically that a PA is a cost-effective solution in CLI. The costs of a

tion to treating CLl²⁶. However, it has never been demonstrated scientifically that a PA is a cost-effective solution in CLI. The costs of a PA reported between 1985-1994 were found to vary from \$12,397 by Yin et~al. who excluded rehabilitation to \$40,563 \pm \$4,729 reported by Mackey et~al. in 1985 who included rehabilitation and longer term follow-up^{12,27}.

In 1997, Luther *et al.* analyzed the cost of PA in a population of institutionalized, nursing home, patients versus previously active noninstitutionalized patients²⁸. The costs were highly variable from \$13,000 in the institutionalized to \$70,000 for the noninstitutionalized PA patient still living at home. The professional nursing care costs after an amputation in the US home has been estimated at \$100,000 per year²⁹. Johnson *et al.* attempted to characterize the costs to the patient and family of home alterations to accommodate an amputee and item ranged from \$700 for a toilet seat to \$25,000

Table 7. Average Cost per Patient - LACI First Pathways.

LAGI First	Pathway	Dx/Eval and Pre-Op Care	Revascularization and/ or Amputation	Post-Op Care	Complications	CLI-Related Rx	Grand Total
40% LACI1	Primary LACI with total limb retention	\$160	\$ 5,213	\$217	\$0	\$256	\$5,840
9% LACI2	Primary LACI + Reintervention	\$352	\$44,438	\$367	\$ 593	\$ 3,487	\$49,237
16% LACI3	Primary LACI with or without reintervention + Amputation	\$206	\$36,699	\$652	\$784	\$2,944	\$ 41,285
65% LACI	First Subtotal	\$197	\$18,315	\$346	\$271	\$ 1,359	\$20,487

Table 8.

Clinicale	No of	% of Pop.	Dx/Eval and	Revascularization and/	Post-Op	Complications	Related Rx	Total Cost
Pathway	Patients		Pre-Op Care	or Amputation	Care		Tallan 100	A. A.
Amputation First	281	67%	\$31	\$22,837	\$276	\$1,672	\$1,474	\$26,289
Bypass Graft First	96	23%	\$116	\$37,271	\$668	\$1,727	\$3,815	\$43,598
PTA First	40	10%	\$206	\$35,922	\$652	\$ 784	\$2,944	\$40,508
If LACI First	N/A	65%	\$ 197	\$18,315	\$ 346	\$ 271	\$1,539	\$20,487

Table 9.

LACI Financial Im	LACI Financial Impact Summary			% of Pop	ulation		25.00
Pathway			Cost/Patient	Study Pop	With LACI	Converted to LACI	Savings with LACI
Amputation First	75%	LACI Use					
		Amp First Subtotal	\$26,289	67%	16,8%	50,5%	\$5 802
Bypass Graft First	50%	LACI Use					
		Bypass First Subtotal	\$43,598	23%	11,5%	11,5%	\$23 211
PTA First	35%	LACI Use					
		PTA First Subtotal	\$40,508	10%	6,2%	3,4%	\$20 021
LACI First		LACI First Subtotal	\$20,487		65,4%		
Summary							
	Ave	erage Total Cost Per CLI P	atient				
	W/	out LACI		\$3	1,638		
	Wit	th LACT		\$ 2	5 373		

\$6,265

[1] Estimated Total Cost per CLI patient, assuming LACI is used 65% of CLI patients, as detailed in model

Average Savings per CLI Patient with LACI adoption

Percentages DNF due to rounding

for concrete wheelchair ramps³⁰. Clearly there are indications that amputations result in a high cost to society by requiring long-term care for the amputees that cannot be rehabilitated to mobility, especially in the elderly age patient^{11-14,29-30}.

PA is associated with high mortality and morbidity and the functionality and quantity of life is reduced for the amputee30-32. IBS and resultant limb salvage have been reported as excellent solutions for treating CLI. Reported advantages of IBS versus PA for CLI include: significant limb salvage rates, decreased 30 day mortality and morbidity, improved functional status and quality of life, cost effectiveness, and improved long term survival^{6,19,31,32-33}. Reports by Thompson et al., Chetter et al., and Johnson et al. have consistently shown improved functional outcomes and quality of life scores in patients after limb salvage versus amputations^{30,34-35}.

In 1992, Cheshire et al. reported that IBS, including secondary procedures, was 47% more cost effective than PA when using autologous vein and 6% more cost effective when utilizing a prosthetic conduit³⁵. In 1997, Panayiotopoulos et al. reported PA as three times more costly that IBS and limb salvage in both diabetics and nondiabetics with costs being PA = \$24,460 and IBS = $$8,640^{36}$. Several other reports document the costs of successful IBS as between \$16,000 and \$20,000³⁷⁻⁴⁰. Mackey et al. reported a 2 year follow up cost for successful IBS of \$20,300 if uncomplicated but quoted costs of \$42,000 when secondary amputations were required13. Korn et al. reported the IBS results in CLI patients with end stage renal disease (ESRD) on dialysis and reported 67% 1-year limb salvage rate. Cost analysis was determined to be \$44,308 per year of limb salvage⁴¹.

Kalra et al. reported the long-term survival after IBS (pedal bypass) in 256 CLI patients. Amputation and ESRD predicted higher mortality (p = 0.014, p = 0.0001, respectively) and overall 5-year survival rates after IBS and limb salvage were 60%6. The 5-year survival rate after an amputation was 26% therefore confirming earlier reports and documenting significantly worse long-term survival for patients suffering an amputation versus those CLI patients achieving limb salvage¹⁹.

Data has only recently been reported on nonsurgical revascularization for treating CLI, despite a greater than fivefold increase in the use of PTA⁴². These early reports evaluate PTA only procedures therefore a cost analysis of more "modern" CLI treatment with the use of stents, plaque excision, endopharmacotherapy, or laser (LACI) does not exist. In 1995, Hunink et al. compared the in hospital costs only for CLI patients treated with PTA or IBS³⁷. The costs of PTA and IBS were respectively \$11,353 ± \$7,658 and \$15,059 ± \$7,313 if uncomplicated. Additional revascularization procedure increases the costs by a mean of \$9,003 in both groups and any amputation or wound debridement further increased the costs by a mean of \$24,766 ± \$2,241. In 1998, Jansen et al. compared IBS and PTA in hospital costs in 583 patients for CLI43. The mean cost of PTA and IBS were \$8,855 and \$12,550 respectively for uncomplicated procedures with additional costs of \$9,345 to \$11,675 for nonfatal and fatal complications. In 2000, Laurilla et al. reported a 41% cost effectiveness of PTA versus IBS in 772 CLI patients⁴⁴. The mean costs of PTA were \$8,855 versus \$16,470 for IBS. The cost of a reoperation-free year was \$4,466 with PTA and \$7,748 with IBS and the costs of a leg-year saved at 3 years was reported at \$3,877 for PTA and \$6,055 with IBS. These recent reports consistently demonstrate the cost-effectiveness of PTA versus IBS.

A comprehensive review of the clinical and economic CLI literature has lead us to several conclusions including:

- There is no evidence that a PA is an overall cost effective treatment for CLI or is more cost effective than revascularization with or without limb salvage. A PA should only be considered in the already institutionalized, immobile advanced CLI patient at high risk for IBS or PTA.
- PTA is more costs effective than IBS.
- PA, IBS, and PTA all require frequent secondary procedures and/or amputations, which are associated with added overall costs.
- There exists no consensus CLI treatment pathway.
- · There remains poor understanding of the overall clinical and economic impact of CLI or amputation to the patient, the family, and to society.

• There exists a need for clinical information and education and even greater need for economic data regarding the treatment of CLI. This independent 2.5 million US patient dataset analysis revealed several interesting clinical practice patterns. An extraordinarily high percentage, 67%, of the RAP received PA as their index or first treatment recommendation. The first treatment recommendation for IBS and PTA were 23% and 10% respectively. This RAP's initial treatment recommendation differed drastically from a 1995 British audit in which 67% of their patients received revascularization. The index procedures in the British series consisted of 38.5% IBS and 28.5% PTA, and only 16% PA²²⁻²³. A similar report from the LEICESTER ROYAL Infirmary revealed a PA rate of only 10% with revascularization attempted in 79% of 188 CLI patients²⁴. It remains disturbingly unclear as to the reason for these differences in clinical practice patterns between our RAP versus other published series. Further insight into clinical practice patterns can also be obtained from a 1997 report by Hallett et al. in the Olmstead County Research Study evaluating IBS, PTA and PA between 1973 and 1992 in a defined community. Approximately 50% of the CLI patients presented with advanced Rutherford Class 4-5-6 and of those requiring amputation, 60-70% were as PA with no vascular assessment or revascularization procedure being performed therefore implying that CLI patients worldwide are treated similarly to the Olmstead County report and this RAP47.

Additional clinical practice pattern data was analyzed in our RAP regarding the CLI diagnostic work up and physician and healthcare provider consultations. An extraordinarily low percentage of CLI patients, 49% of this RAP, had any vascular assessment before a recommendation for PA. The RAP pathway had a recommendation of ABI and angiography in only 35% and 16% respectively before a first treatment recommendation for PA. This clinical practice pattern is especially disturbing when considering the excellent limb salvage results reports with pedal bypass, PTA, and LACI^{23,33,45}. A 50% limb salvage rate has even been reported with "blind exploration" and pedal bypass in severe CLI patients without identifiable distal bypass targets during angiography⁵⁰.

From the economic standpoint, this practice pattern is also disturbing when considering that the total costs of treating CLI in the US alone is estimated at between \$10-20 billion per year³. It is estimated that just a 25% reduction of amputations could save \$2.9-3.0 billion in US healthcare expenditures³. Further economic data supporting limb salvage include the known higher costs of amputations and related periprocedural rehabilitation as compared to IBS and PTA and limb salvage. Additionally, the annual cost of follow-up or long-term care and treatment for a patient has been estimated at approximately \$49,000 after an amputation and \$600 after limb salvage after PTA or IBS^{3,16,48-49}.

Study Limitations

- The 18-month study period represents a retrospective cross-section of time. The analysis did not prospectively collect data on the procedures included in the RAP or LACI patient populations.
- Procedure coding is not lesion or limb specific.
- Rates and costs of complications in the RAP may be understated because inpatient records typically contain many diagnosis codes

- and the first few codes are normally devoted to the underlying condition and major comorbidities.
- Procedure and CPT codes are specific to problems with an amputated stump, it was possible to identify amputation-related complications more thoroughly than PTA or IBS complications.
- The RAP analysis did not include CLI patients who did not receive an amputation.
- The RAP and LACI trial patients were both highly selected and different groups, not truly comparable groups, therefore obviating any definitive conclusions.
- There were significant assumptions made regarding the LACI phase II trial and their applicability to this RAP therefore conclusions based on these calculations are subject to bias.

Conclusion

in conclusion, the clinical and economic costs and consequences of CLI and amputations are both staggering and unappreciated and it is likely that CLI is approaching global epidemic proportions. Strong clinical and economic data currently exists supporting an aggressive approach for revascularization and limb salvage in almost every patient with CLI. A reasonable assumption for this study's disturbing clinical practice pattern favoring a PA versus a revascularization first pathway is that many CLI patients are seen first, or referred first, to clinicians who cannot provide revascularization and therefore provide a pathway for amputation. As is true in most global healthcare epidemics, if a positive impact is to be made then it must start with information and education and progress to global commitments to enhance awareness and provide clinical and economic cost effective treatment. Despite the stated limitations, assumptions and potential biases of this analysis, the utilization of a LACI pathway first treatment strategy may provide clinical benefits and economic cost savings in treating patients with CLI.

Acknowledgments

The authors would like to thank Mrs. Kelly Tilbe for her technical help with manuscript preparation.

References

- 1. U.S. Department of Health and Human Services. National Center for Health Statistics. National Hospital Discharge Survey: Annual Summary with Detailed Diagnosis and Procedure Data. Data from the National Hospital Discharge Survey. Series 13. 1983-2000.
- 2. Mayfield JA, Reiber GE, Maynard C, *et al.* Trends in lower limb amputation in Veterans Health Administration, 1989-1998. *J Rehabil Res Dev* 200;37(1):23-30.
- 3. Yost, ML. Peripheral Arterial Disease: A Report by The Sage Group. 2004; Vol. II.
- 4. Anonymous. Second European Consensus Document on Chronic Critical Limb Ischemia. Eur J Vasc Surg 1992;6:Suppl A:1-32
- 5. Fisher RK, Harris PL. Epidemiological and economic considerations in the critically ischemic limb. "Critical Limb Ischemia" 1999.p.19-25.
- 6. Kalra M, Gloviczki P, Bower TC, et al. Limb salvage after successful pedal bypass grafting is associated with improved long-term survival. *J Vasc Surg* 2000;33:6-16.

- 7. Hallett JWJ, Bryne J, Gray DT, *et al.* Impact of arterial surgery and balloon angioplasty on amputation: a population based study of 1155 procedures between 1973-1992. *J Vasc Surg* 1997;25:29-38.
- 8. Dormandy JA, Ray S. The natural history of peripheral arterial disease. In: Tooke JE, Loew GD, editors. A textbook of vascular medicine. London: Arnold;1996.p.162-75.
- 9. Hobson RW, Lynch TG, Padberg FTJ, *et al.* Results of revascularization and amputation in severe lower extremity ischemia: a five-year clinical experience. *J Vasc Surg* 1985:2:174-85.
- 10. Transatlantic Inter-Society Consensus (TASC) on Management of Peripheral Arterial Disease (PAD). *J Vasc Surg* 2000;31:S271.
- 11. Gregg RO. Bypass or amputation? Concomitant review of bypass arterial grafting and major amputation. *Am J Surg* 1985;149:397-402.
- 12. Mackey WC, McCullough JI, Callow AD, et al. The costs of surgery for limb-threatening ischemia. *Surgery*1986;99:26-35.
- 13. Raviola CA, Nichter LS, Moore WS, *et al.* Costs of treating advanced leg ischemia. Bypass graft versus primary amputation. *Arch Surg* 1988;123:495-496.
- 14. Paaske WP, Lausten J. Femorodistal bypass grafting: quality of life and socioeconomic aspects. *Eur J Vasc Endovasc Surg* 1995;10:226-230.
- 15. Wolfe JH, Wyatt MG. Critical and subcritical ischemia. *Eur J Vasc Endovasc Surg* 1997;13:578-582.
- 16. Transatlantic Inter-Society Consensus (TASC) on Management of Peripheral Arterial Disease (PAD). *J Vasc Surg* 2000;31:1-296.
- 17. Pentacost MJ, Criqui MH, Dorros G., *et al.* Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. *Circulation*. 1994;89:511-531.
- 18. Wolfe, JHN. Defining the outcome of critical ischaemia: a one-year prospective study. *Br J Surg.* 1986;11:153-157.
- 19. Panayiotopoulos YP, Tyrrell MR, Taylor PR, *et al.* Outcome and cost analysis after femorocrural and femoropedal grafting for critical limb ischaemia. *British J Surg* 1997;84:207-212.
- 20. Tordoir JH, van der Plas JP, Jacobs MJ, Kitslaar PJ. Factors determining the outcome of crural and pedal revascularization for critical limb ischaemia. *Eur J Vasc Surg.* 1993 Jan;7(1):82-6.
- 21. Arora S, LoGerfo FW. Lower extremity macrovascular disease in diabetes. *J Am Podiatr Med Assoc.* 1997 Jul;87(7):327-31.
- 22. Fisher, RK, Harris PL. Epidemiological and economic considerations in the critically ischemic limb. *Critical Limb Ischemia* 1999; 19-25.
- 23. Anonymous. Critical Limb Ischaemia: management and outcome. Report of a National Survey. The Vascular Surgical Society of Great Britain and Ireland. *Eur J Vasc Endovasc Surg* 1995; 10:108-113.
 - 24. Fisher, RK, Harris PL. Critical Limb Ischemia 1999.
- 25. Laird JR. Laser angioplasty for critical limb ischemia (LACI); results of the LACI phase 2 clinical trial. Presented at ISET annual meeting, January 2003;www.iset.com.
- 26. Stoney RJ. Ultimate salvage for the patient with limb-threatening ischemia. Realistic goals and surgical considerations. *Am J Surg.* 1978 Aug;136(2):228-32.
- 27. Yin D, Baum RA, Pentecost MJ, *et al.* Cost-effectiveness of MR angiography in cases of limb-threatening peripheral vascular disease. *Radiology* 1995;194:757-764.
- 28. Luther M. Treatment of chronic critical leg ischemia. Ann Chir Gynaecol 1997;86:S213.

- 29. Callow AD, Mackey WC. Costs and benefits of prosthetic vascular surgery. *Int Surg* 1988;73:237-240.
- 30. Johnson BF, Evans L, Beard ID, *et al.* Surgery for limb threatening ischemia: a reappraisal of the costs and benefits. *Eur J Endovasc Surg* 1995:9:181-188.
- 31. Pemler BA. Vascular disease in the elderly patient. *Surg Clinical N Am* 1994;74:200-216.
- 32. Luther M. Surgical treatment for chronic critical leg ischaemia: a 5-year follow-up of socioeconomic outcome. *Surg J Endovasc Surg* 1997;13:452-459.
- 33. Pomposelli FB, Kansal N, Logerfo FW, *et al.* A decade of experience with dorsalis pedis artery bypass: analysis in more than 1000 cases. *J Vasc Surg* 2003;37:307-315.
- 34. Thompson MM, Sayers RD, Reid R, *et al.* Quality of life following infragenicular bypass and lower limb amputation. *Eur J Vasc Surg* 1995;9:310-313.
- 35. Cheshire NJW, Wolfe JHN, No one MA, *et al.* The economics of femorocrural reconstruction for critical limb ischaemia with and without autologous vein. *J Vasc Surg* 1992;15:167-175.
- 36. Panayiotopoulos YP, Tyrell MR, Taylor PR, *et al.* Results and costs analysis of distal (crural/pedal) arterial revascularization for limb salvage in diabetic and non-diabetic patients. *Diabetic Medicine* 1997;14:214-220.
- 37. Hunink MG, Cullen KA, Donaldson MC. Hospital costs of revascularization procedures for femoropopliteal arterial disease. *J Vasc Surg* 1994;19:632-641.
- 38. Paaske WP, Lausten J. Femorodistal bypass grafting: quality of life and socioeconomic aspects. *Eur J Endovasc Surg* 1995;10:226-230.
- 39. Myrhe H, Wisto E. What are the costs of critical limb ischemia? *Critical Ischemia* 1996;5:83-87.
- 40. Singh S, Evans L, Datta D, et al. The costs of managing lower limb-threatening ischemia. Eur J Endovasc Surg 1996;12:359-362.
- 41. Korn P, Hoenig SJ, Skillman JJ, *et al.* Is lower extremity revascularization worthwhile in patients with end stage renal disease? *Surgery* 2000;128:472-479.
- 42. Pell JP, Whyman MR, Fowkes FG, et al. Trends in vascular surgery since the introduction of percutaneous transluminal angioplasty. *Br J Surg* 1994;81:832-835.
- 43. Jansen RM, Cullen KA, Hunink MGM, *et al.* Cost-identification analysis of revascularization procedures on patients with peripheral arterial occlusive disease. *J Vasc Surg* 1998;28:617-623.
- 44. Laurilla J, Brommels M, Edgren J, *et al.* Cost effectiveness of percutaneous transluminal angioplasty (PTA) versus vascular surgery in limb-threatening ischeamia. *International J Angioplasty* 2000;9:214-219.
- 45. Allie, et al. Excimer Laser-Assisted Angioplasty in Severe Infrapopliteal Disease and CLI: The CIS "LACI Equivalent" Experience. Vascular Disease Management 2004, October, 14-22.
- 46. Pomposelli FB, Marcaccio EJ, Burgess Am, *et al.* Dorsalis pedis arterial bypass: durable limb salvage for foot ischemia in patients with diabetes mellitus. *J Vasc Surg* 1995;21:375-384.
- 47. Hallett JW, Byrne J, Gayari MM, *et al.* Impact of arterial surgery and balloon angioplasty on amputation: A population-based study of 1155 procedures between 1973 and 1992. *J Vasc Surg* 1997; 25:29-38.
- 48. Muradin GSR, Hunnink MGM. Cost and patency rate targets for the development of endovascular devices to treat femoropopliteal arterial disease. *Radiology* 2001; 218:464-9.

- 49. Muradin GSR, Bosch JL, Stinjnen T, Hunink MGM. Balloon dilation and stent implantation for treatment of femoropopliteal arterial disease: meta-analysis. *Radiology* 2001; 221: 137-45.
- 50. Chang RW, Pellisier JM, Hazen GB. A cost-effectiveness analysis of total hip arthroplasty for osteoarthritis of the hip. *JAMA* 1996; 275 (11): 858-65.
- 51. Allie, DE Hebert CJ, Walker, CM. Multidetector Computed Tomography Angiography: Two decades of evolution in this imaging modality have produced some powerful and unprecedented options. *Endovascular Today*, March 2004, 20-28.



June 20, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am concerned regarding Medicare's consideration to implement a competitive acquisition program for vendors of durable medical equipment. As an Occupational Therapist, I evaluate and supply pre-fabricated on a daily basis to surgical and medical patients. As a trained professional, I can fit and distribute an effective and comfortable splint without any delay. This allows adequate healing and compliance from the patient, minimizes complications, and prevents problems as seen by ill-fitted splints.

Appropriately fitted splints in a timely fashion will save healthcare dollars. It is felt that our splint application, pricing, education and instruction are appropriate and necessary for Care of our Medicare and Medicaid patients. Untrained individuals are not able to provide this healthcare service that will maintain or obtain functional outcomes in their hand use with activities of daily living.

Thank you for your time and attention to this important matter.

Sinceredy,

JoAnn Shropshire, TR/CI

Occupational Therapist/ Certified Hand Therapist

275)

Caribbean Home Medical Equipment, Corp

Venta y Alquiler de Equipos Medicos 8155 Calle Concordia Suite 104 Ponce, P.R. 00717-1599 Tel/Fax: (787) 284-5058

Center for Medicare & Medicaid Services

Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express that one of the reasons why we should not be considered in the competitive bidding process or at least not to be considered in the first 10 MSA's (Metropolitan Statistic Area); is the language barrier that currently exists between Puerto Rico and the United States, given that the majority of the islanders are native Spanish speakers. And the implementation of this program will be at a high cost for many suppliers and it will cause a decrease in supplier's access to beneficiaries, resulting in a less competitive market.

Respectfully yours.

PEDRO A. SANTIAGO

Presidente

Jill Hentrup 3027 Pebble Brook Jeffersonville, IN 47130



Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

Dr. McClellan:

I am a physical therapist practicing in the states of IN and KY. I have been a licensed PT for 15 years and have a wide range of clinical experience including inpatient hospital, inpatient rehab, home health and long-term care and outpatient services. In those various settings, I have evaluated and treated many patients with orthopedic and neurological problems that affect their daily lives in the way of impaired mobility, impaired activities of daily living and impaired ability to perform their necessary job duties. I currently am focusing my practice in an outpatient clinic where I make recommendations for and modifications to orthotics and other durable medical equipment on a regular basis. Recommending appropriate equipment and devices is an integral part of the plan of care for physical therapy.

As a physical therapist, I am often the professional who recommends a certain device to assist a patient with their impairment. The adjustment and/or modification of the device should be based on clinical assessment of correct fit, correct use of the device by the patient and if the device is providing the expected outcome. This clinical assessment can only be performed by a licensed physical therapist. At times, the recommended device does not provide the outcome I originally expected and a different type of device must be tried. For example, a patient comes to me with a recent fracture or severe sprain and will need immobilization. If we try one splint or brace and it does not provide appropriate stabilization, another one must be available to try immediately. This is in the best interest of the patient to prevent further injury. Requiring the patient to travel to another site to receive a brace that may or may not provide proper immobilization is a detriment to him/her. Even when an off-the-shelf item works for a particular patient, it still may need some type of adjustment or modification to fit properly. For example, a patient with hemiplegia may use an ankle-foot orthosis (AFO) to assist with ambulation. A prefabricated AFO may work fine except for one area of the foot where there is friction or pressure. I adjust the orthotic or modify it to eliminate the risk of skin breakdown. This is something I routinely do in the clinic.

Another situation that occurs is when one brand of brace, splint or other DME does not work for the patient. Each brand fits differently, has various features and some are not available in the size the patient needs. For example, a patient with a fractured ankle

comes to me for a CAM walker. The first one I apply does not fit properly and does not provide adequate stabilization. I apply a different brand; it fits well and provides adequate stabilization. If the patient's only option was the first brace, the fracture would likely not heal properly. Since I deal with various types and brands of DME on a regular basis, I am able to make an informed *clinical* decision regarding which brand and device is the best for that individual patient. Often I discuss specific patient issues with the attending physician and together we determine which brand will work best for that individual. Many physicians recognize my expertise in this area and ask my opinion about the options.

In addition to issuing the DME and adjusting it as needed, I also provide education and instructions to the patient regarding purpose of the item, care of the item, proper use of the item, a wearing schedule if appropriate and what to do in case any complications or questions arise. In the case of an ambulatory device, it is my professional responsibility to ensure patient safety with the device. Gait training may be necessary if they are using a device for the first time or adjustments may be needed if there are co-morbidities that may affect their ability to use the device correctly. If the patient is only dealing with a DME supplier, who is going to answer questions, inform them of the above and make clinical judgments as above? Again, such *clinical* judgments can only be made by a licensed physical therapist.

As a practicing physical therapist that recommends, adjusts, modifies and issues various DME on a daily basis, I urge CMS to revise the regulations and recognize the need for licensed physical therapists to:

- Furnish DME that are critical to the care of our patients
- Issue DME in a timely and safe manner
- Adjust and modify orthotics and other DME
- Recommend specific brands of DME to prevent adverse medical outcomes

Dr. McClellan, I want to thank you for considering my opinions and comments. I hope the clinical examples I provided will assist you and the agency in making a decision that will be in the best interest of all patients covered by Medicare.

Sincerely,

Jill Hentrup, PT, MHS

All Hentrup PT



June 26, 2006

Fellow, American Academy of Podiatric Management

Kevin McDonald, D.P.M.
Diplomate, American Board of Podiatric Surgery
Diplomate, American Board of Podiatric Orthopedics
Fellow, American College of Foot and Ankle Surgeons

Mark McClellan, MD, PhD Administrator, CMS P.O.B. 8013 Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Dr. McClellan,

I practice podiatry in two small towns in North Carolina – neither town has an orthopedist and both towns have limited options for DME products. Many of my patients are elderly, have limited mobility and are unable to drive. Making a trip to the doctor is quite an ordeal for many of them. Thus, it would be best for them to receive any medically required DME products at the time of their podiatric visits and not have to then travel out of town for their treatments.

I believe that CMS should use the 1861(r) definition of a physician when finalizing the regulations for dispensing DME products from physician offices. This is the most efficient and beneficial use of CMS resources. It is also best for my patients.

Please use definition 1861(r) in regulating the competitive acquisition program for DME.

Sincerely,

Kevin McDonald, DPM

JUNE 19,2006

TO:

CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES

ATTN: CMS-1270-P: PO BOX 8013

FR:

IV CARE OF SAN ANTONIO D.B.A.: NETCARE PHARMACY

6428 BANDERA RD SAN ANTONIO, TX 78238

PROVIDER ID: MEDICARE: 1237510002

MEDICAID: 167964901 / 16796402

AS A DME SUPPLIER, NETCARE PHARMACY STRONGLY OBJECTS TO THE IDEA FOR A DME COMPETITIVE BIDDING PROPOSAL. REASON #1: MANY BENEFICIARIES ARE IN NEED OF DME SUPPLIES IMMEDIATELY AND CAN NOT WAIT FOR THEIR SUPPLIES TO COME IN BY MAIL. THEY ALSO REQUIRE SOME KIND OF DEMONSTRATION ON HOW TO USE THEIR PRODUCTS AND SUPPLIES, WHICH REQUIRES A PHARMACIST TO PHYSICALLY SHOW THE PATIENT HOW TO PROPERLY USE THESE ITEMS. REASON #2: WHEN IT COMES TO DME SUPPLIES PATIENTS TEND TO WAIT TILL THE LAST FEW DAYS, IF NOT THE LAST DAY, WHEN THEY ARE GOING TO RUN OUT. USUALLY THEY ARE UNABLE TO WAIT THE EXTENDED MAIL ORDER TIME TO RECEIVE SUPPLIES BY MAIL. REASON #3: MANY PHYSICIANS SWITCH OUT THE PATIENTS DME PRODUCTS AND SUPPLIES OFTEN WHEN EVER UPDATED VERSIONS ARE AVAILABLE. WHICH CAUSES THE PATIENT TO BE IN NEED OF NEW SUPPLIES AND OR DEVICES. REASON #4: WE DISAGREE WITH CMS' ALTERNATIVE PROPOSAL THAT WOULD LIMIT BENEFICIARIES' CHOICE OF A DME PROVIDER. THIS PROPOSAL WOULD SEVERELY RESTRICT BENEFICIARIES' ACCESS TO NEEDED ITEMS AND SUPPLIES. LIMITING BENEFICIARIES' ACCESS OF CHOICE TO MANDATORY MAIL SERVICE IS NOT APPROPRIATE FOR DME PRODUCTS AND SUPPLIES, ITEMS THAT BENEFICIARIES NEED CONVENIENT AND FREQUENT ACCESS TO. THE COMPETITIVE BIDDING PROGRAM SHOULD NOT INCLUDE COMMON DMEPOS PRODUCTS AND SUPPLIES.

THANK YOU,

MIKE BUCHMEIER RPH, PHARM-D

NETCARE PHARMACY

(249)

6/25/06

Mark B. McClellan, MD. PhD Administrator Centers for Medicare & Medicaid Services Dept. of Health and Human Services Áttn. CMS-1270-P P. O. Box 8013 Baltimore, MD 21244-8013

Dr. McClellan,

The purpose of my letter is to express some concerns I have relative to the "Proposed Rule for Competitive Acquisition of Certain DMEPOS."

I am a physical therapist with a hospital based practice in rural North Dakota. There are only 2 DME providers in my area with I located 90 miles from here and the other a 120 miles from my facility. I frequently work with patients who have diagnosis of plantar fascitis, Achilles tendonitis, and posterior tibial tendonitis. After a thorough biomechanical assessment and evaluation the use of a trial with orthotic is often a portion of the recommended treatment/intervention. Often this does involve modification to a pre-fabricated off-the-shelf orthotic in order to customize to the patient's individual needs. If my patients are required to travel to obtain their orthotic I am concerned that it would have a negative impact for them. There certainly would be a delay to starting treatment and secondly I am sure some would not even make the trip. With gas prices as they are a 180-240 mile round trip causes a financial hardship for persons on a limited/fixed income.

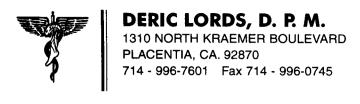
Another concern I have is with knee orthosis used in the treatment of patello-femoral syndrome and patellar malalignments. There are a variety of orthosis on the market with a variety of features. I am finding that the DME providers are only caring certain brands and do not have the access to all types and brands. This would limit my choices as a clinician.

I appreciate having the opportunity to provide you with my concerns and wish to thank you for your help with this important issue.

Sincerely,

Wade Burgess, PT P. O. Box 503

Rolla, ND 58367





June 30, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services ATTN; CMS-1270-P P. O. BOX 8013 Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am writing you to express how important it is for CMS to change the definition from 1861®(1) to 1861®(3).

I have been practicing in Placentia, California for the past 25 years and have a current DME supplier number.

It is so important when treating my patients that I have control over the type of supplies that are being dispensed. This cuts down on the recovery time and decreases the risk for complications.

Therefore, I urge CMS to modify the physician definition from 1861®(1) to 1861®(3).

Thank you for your consideration.

Sincerely,

Deric Lords, DPM



2944 Salem Circle Racine, WI 53406-1828 June 26, 2006

Centers for Medicare and Medicaid Services Dept. of Health and Human Services Attention: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

To All It May Concern:

I am a Registered Occupational Therapist and a Certified Hand Therapist. As such I have specialized skills and expertise in the disease process of upper extremity disorders. A component of the care that I provide is the fabrication/provision and fitting of orthoses. The patient's needs are thoroughly evaluated in order to determine the appropriate orthoses. Factors include the disease process, extent of injury, structures involved, functional and ADL needs, ergonomics, purpose/goal of orthotic, precautions, monitoring and future orthotic needs.

I am writing to address my concerns regarding the Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a particular orthosis. As a result, it is not guaranteed that a beneficiary will be able to obtain a specific orthosis in their local area, potentially limiting their access to the needed orthosis. Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. Frequently we as therapists must respond immediately to changing conditions in a patient's medical condition. When these occur we must alter or make modifications to their orthosis.

I am concerned about the legal and ethical issues I may face when a patient comes to me after they have been issued an inappropriate orthosis by another entity. Do I adjust the orthosis myself and assume liability for an orthosis that I did not supply to this patient? Or do I send the patient back to the original supplier knowing that they may be inadequately cared for? Neither scenario is acceptable.

I ask that this proposal be abandoned and that we as qualified, trained therapists continue to meet the needs of our patients including evaluation, selection, fitting and monitoring of their orthotics.

Sincerely,

Kith M. Chapetta-Kullacki, OTR/L, CHT Ruth M. Chiapetta-Kulbacki, OTR/L, CHT



-Melbourne Podiatry Associates

Surgery of the Foot and Ankle

Briant G. Moyles, D.P.M. Richard C. Wilson, D.P.M.

Diplomate American Board of Podiatric Surgery • Fellow American College of Foot and Ankle Surgeons

June 8, 2006

Mark B. McClellan, M.D., Ph.D., Administrator Center for Medicare and Medicaid Services Department of Health and Human Services ATTN: CMS-1270-P P.O. Box 8013 Baltimore, MD 21244-8013

RE: Medicare Program, Competitive Acquisition for DME

Dear Dr. McClellan:

As a podiatric physician who has been in practice for over 25 years, I am writing to seek your opposition to the proposed rule Medicare Program – Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and Other Issues.

As you know, this rule would include physicians in a competitive acquisition program for certain DME items. I urge CMS to reconsider its original proposal and to exclude physicians, including podiatric physicians, from the competitive bidding requirement.

Having provided DME supplies for both Medicare and non-Medicare patients for many years, I have found that the physician as supplier is in the best position to provide appropriate care for patients. As a supplier of these devices, I am able to select the devices that I consider to be the best quality for the patient and individualize it for that patient. I am also able to make sure that the patient uses the devices properly. This provides appropriate care for patients, as well as giving them the convenience of getting the devices at the office. I have seen too many cases where patients under managed care contracts have been forced to go elsewhere for their DME items, only to be given substandard items and in some cases, the completely wrong item, regardless of my prescription. The competitive bidding proposal that CMS is considering would greatly reduce the quality of care for patients. This being the case, it is essential that physicians be excluded from this rule.

Physicians currently are responsible only for about 3.1% of the total DME POS allowed charges. Their exclusion from competitive bidding would not result in any significant savings to CMS, but would harm patient care. I strongly urge you to exempt physicians from this competitive bidding rule.

Thank you for your attention to this matter.

Sincerely,

Richard C. Wilson, DPM

Retry Muhon

RCW/jmp

211 East New Haven Avenue • Melbourne, Florida 32901 • (321) 723-2022 • 723-3500 • Fax (321) 723-1945 1310 W. Eau Gallie Blvd., Suite E • Melbourne, Florida 32935 • (321) 255-3338 • Fax (321) 253-9643

FOOT AND ANKLE

ASSOCIATES

JEFF NIESPODZIANY D.P.M., F.A.C.F.A.S. DOUG KOLMODIN, D.P.M.

4455 Edison Lakes Parkway, Suite 200A • Mishawaka, IN 46545 (574) 259-9668 • Fax: (574) 259-9671'

Email:ninftcare@aol.com

June 26, 2006

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1270-P

Dear Dr. McClellan:

We are writing in response to the requested changes concerning Podiatric physicians and their ability to prescribe and dispense DMEPOS type items. Podiatric physicians are licensed by each and every state in the United States to diagnosis and treat their patients. Very often these patients are elderly or lacking the means to go from place to place to receive prescribed medical supplies or equipment. Eliminating this very necessary service may reduce the level of care received by patients. Then, of course, patients would suffer at various levels.

Please continue to allow Podiatric physicians to function at the capacity of fellow physicians.

Sincerely;

Dr. Jeff Niespodziany Dr. Doug Kolmodin